NY - Physician Assistants: Physicians may assign prescribing authority to registered PAs. PAs may not prescribe controlled substances.

NC - Physician Assistants: PAs are authorized by law to write prescriptions under conditions specified by the state board of medical examiners. PAs may prescribe drugs from a medical board-approved formulary that excludes controlled substances and parenteral preparations except insulin, immunizations, serum, epinephrine and benadryl. A prescription may not indicate a refill except birth control pills and may be for no more than 100 dosage units or a one-month supply.

Nurses: ARNPs may prescribe non-controlled substances under the supervision of a physician.

ND - Physician Assistants: PAs may prescribe controlled substances, except Schedule II, as agents of their supervising physicians.

Nurses: The Board of Nursing is responsible for delegating prescribing authorities. Once approved by the Board, nurses may prescribe drugs under the supervision of a physician. The types of drugs that a nurse can prescribe are determined by their area of expertise (six practice areas) designated by the Board.

OR - Physician Assistants: Physicians may delegate to PAs the authority to administer and dispense limited emergency medications and to prescribe. The medical board's Physician Assistants Committee is authorized to review applications for prescribing and dispensing privileges and to recommend a formulary that may include all or part of Schedules III through V. To prescribe Schedules II through V controlled substances, PAs must be registered with DEA.

PA - Physician Assistants: Regulations are currently under development that would allow PAs to prescribe and dispense drugs at the direction of licensed physicians. The rules include a formulary that excludes Schedules I and II controlled substances. Until the regulations are promulgated PAs have no prescribing authority.

RI - Physician Assistants: PAs may write prescriptions and medical orders. PAs employed by physicians, HMOs or other health care delivery organizations may prescribe legend medications and Schedule V controlled substances, medical therapies, device and diagnostics according to guidelines established by their employers. Guidelines are updated annually. PAs prescribing controlled substances must register with the state drug control division and with DEA.

Nurses: NPs have prescriptive authority for legend drugs but not for controlled substances.

SC - Physician Assistants: Regulations are currently under development that would grant PAs dependent authority to prescribe Schedule V controlled substances. The regulations would also establish a formulary and appropriate protocols. Until these regulations are developed and implemented PAs have no prescribing authority.

Nurses: Nurses are certified through the Board of Nursing for dependent prescribing authority.

SD - Physician Assistants: PAs can communicate information regarding Schedules III-V drugs to the pharmacy either in writing or by phone. PAs must act as agents of physicians to issue prescriptions for controlled substances; the physician decides on drug, dosage, amount and length of therapy.

Nurses: Certified NPs may prescribe under a practice agreement with the supervising physician. NPs act as the agent of the primary supervising physician in providing and prescribing, except for Schedule II controlled substances.

TN - Nurses: Certified NPs may apply to the Board of Nursing for a "certificate of fitness" with privileges to write and sign prescriptions and/or issue non-controlled legend drugs.

TX - Physician Assistants: Physicians may authorize PAs to administer, provide or carry out a prescription drug order (i.e., complete a prescription pre-signed by the supervising physician) in medically underserved areas.

Nurses: ARNPs have prescriptive authority under standing orders or protocols; prescriptions must be "presigned." To be authorized to prescribe the ARNP must serve certain medically underserved populations.

UT - Physician Assistants: PAs may, in accordance with an approved utilization plan, prescribe Schedule IV and V controlled substances for a period not to exceed seven days.

Nurses: All NPs who practice with a physician can apply for prescriptive privileges in accordance with protocols between the NP and physician. NPs can prescribe controlled substances III-V.

VT - Physician Assistants: PAs may prescribe only drugs selected by the supervising physician from the board-approved drug list. The board's approved drug list contains 25 categories. Some categories, such as heavy metal antagonists, antineoplastics, coagulation agents, cardiovascular drugs and oxytoxics, require additional protocols describing in detail the conditions under which the PA will be prescribing. The physician may delegate the prescribing of controlled substances in any of the categories.

VA - Physician Assistants: Regulations are currently being developed that would give PAs dependent authority to prescribe non-controlled substances. The regulations will include a formulary of specific drugs and devices a PA may prescribe under a written protocol with the supervising physician.

Nurses: ARNPs may prescribe most Schedule VI drugs under the supervision of a licensed physician.

WA - Physician Assistants: PAs may issue written or oral prescriptions when approved by the board and assigned by the supervising physician. Prescriptions for drugs in Schedule II-V may be issued for patients under the care of the sponsoring physician.

WV - Physician Assistants: PAs in all settings may issue prescriptions at the direction of their supervising physician. A state formulary excludes Schedule I and II controlled substances, anticoagulants, antineoplastics, radiopharmaceuticals, general anesthetics, and radiographic contrast materials. Drugs listed under Schedule III are limited to a 72-

hour supply without refill. Medical board rules exclude parenterals, except insulin and epinephrine, from the formulary.

Nurses: ARNPs have limited authority to prescribe, including some controlled substances.

WI - Physician Assistants: Supervising physicians may direct a PA to prepare a prescription order for non-controlled substances if the PA prepares the prescription order only in patient situations specified and described in written protocols; the PA consults directly with the physician, when practicable, prior to preparing a prescription; and the prescription contains the name and address of the physician and PA.

WY - Physician Assistants: PAs may prescribe medications as an agent of the supervising physician, except for Schedule I and II controlled substances. When prescribing controlled substances the supervising physician's DEA number is used.

Nurses: Current legislation states that nurses have prescribing and dispensing capabilities under a "collaborative agreement" with a physician. The Attorney General is currently in the process of determining whether this "collaborative agreement" constitutes independent or dependent prescribing authority. Until the issue is resolved nurses do not have prescriptive authority for controlled substances.

Cardinal Health

TO: Tom Blaylock/*National Specialty Serv.*
John Dewees/*Marmac*
Paul Exley/*Ohio Valley*
Rick Gliot/*Chapman*
Pat Jensen/*Syracuse*
Ben Jones/*Bailey*
Brian Landry/*Mississippi*
Doug Pace/*Florida*
John Roth/*Solomons*
Roy Stromski/*Daly*
Carol Verrastro/*Ellicott*

CC: George Bennett/*Dublin*
Pete Westermann/*Dublin*
Linda Zarlengo/*Dublin*

DATE: September 7, 1993

FROM: Steve Reardon

SUBJ: **DEA Registrations**

At a recent meeting with DEA in Washington, D.C., Jim Pacella, DEA's Policy Unit Chief, discussed DEA registration verification issues with NWDA's Regulatory Affairs Committee. The points Mr. Pacella made are summarized as follows:

- Local DEA offices have been instructed not to verify DEA registrations verbally via the telephone. The reason is that certain wholesalers were using this as the sole means of verifying their customers' DEA registration numbers. Despite these instructions, however, I am aware of local offices that continue to verify numbers over the telephone. My recommendation is that if, in emergency situations, your local DEA office will provide this service, then you should continue to use it as long as the verification is documented on a Regulatory Agency Contact Form. This method, however, should not replace your existing Registration Verification Procedure.

- Local DEA offices should not be verbally issuing DEA registration numbers upon inspections of new registrants. DEA's policy is that a person is not registered until the registration certificate is issued. Although DEA Washington denies it, I know that local DEA offices continue this practice. Again, if your local DEA offices operate in this manner, you should take advantage and service your customer as long as you document the verification and request from your customer a copy of the certificate immediately upon receipt.

- A 60-90 day registration renewal grace period exists during which time you can continue to sell to customers who have yet to receive their renewed registration. I would recommend that you obtain a copy of the customer's renewal application and processed check if possible.

- For those accounts who operate on a physician's DEA registration, the physician's name should also appear on the records for that account; i.e., the invoice should show:

ABC Clinic
Dr. John Smith

If you have any questions regarding these issues, please call.

U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

(2)

NOV 2 9 1993

Ms. Diane P. Goyette
Director of Regulatory Affairs
National Wholesale Druggists' Association
1821 Michael Faraday Drive
Suite 400
Reston, Virginia 22090-5348

Dear Ms. Goyette:

This is in response to your correspondence of November 4, 1993, requesting information on any written clarification of security issues prepared by the Drug Enforcement Administration concerning specifications for cages and security containers. The Office of Diversion Control (OD) routinely disseminates security information to its field offices as part of its effort to insure uniform interpretation and application.

Recently, two security notices were prepared and distributed to the field Diversion Investigators. One addressed the new GSA specification revision for Class 5 security containers and the other addressed the cage configuration utilized for the storage of Schedule III-V controlled substances. The following is a synopsis of those two notices:

Class V Security Containers: This notice covered the General Services Administration's (GSA) specification revisions for improved, manipulation-resistant combination locking devices used on GSA Class 5 and 6 security containers and vault doors. This revision was intended to counter surreptitious entry using an auto-dialing device and/or radiological or emanations analysis. As a result, the specifications where changed to read as follows: "20 man-hours against surreptitious entry; 30 man-minutes against covert entry; and 20 man-hours against radiological techniques."

This notice further stated that only one lock, the Mas-Hamilton X-07, meets the new specifications without modifications. It further explained that the security

standards listed in 21 CFR 1301.72(a)(1)(i) and 1301.72(a)(3)(ii) have not been revised to agree with the new GSA specifications.

- Lastly, the notice re-emphasized the fact that the regulations do not require a registrant to utilize a GSA Class 5 container. Instead, the regulations spell out the minimum security requirements for a security container or vault door used for the storage of Schedule I and II controlled substances. There are several security containers which, when equipped with a Group 1-R three position dial-type combination lock, meet the current Federal requirements.

Schedule III-V Cage Specifications: This notice clarified the construction specifications for cages utilized for the storage of Schedule III-V controlled substances. As described in 21 CFR Section 1301.72(b)(4)(ii), a cage's mesh construction cannot have openings greater than 2 1/2" across the square. The confusion existed with the phrase "across the square" which is not a standard size measurement used by cage manufacturers to describe mesh fabric. The industry measurement for mesh size is the minimum distance between the wires forming the parallel sides of the mesh.

Some field offices were interpreting this measurement to be the diagonal distance from corner to corner, while other offices were using the distance between the parallel sides of the mesh configuration. A size comparison of the two options shows a substantial mesh size difference.

Based on this comparison and the intent of this regulation, it was decided that the 2 1/2" measurement has to be interpreted as the greatest point of separation in the mesh configuration. Another way of describing this regulation requirement is that the mesh size cannot exceed 1 3/4" by industry standards.

I trust that the above information adequately addresses your request. If you have any additional questions, please do not hesitate to contact this office.

Sincerely,

William C. Reinig

William C. Reinig
Security Specialist
Office of Diversion Control

Cardinal Health

TO Tom Blaylock
Brendan Connolly
Paul Exley
Ben Jones
David Kozaczka
Brian Landry
George Oughterson
Doug Pace
John Roth
Roy Stromski
Mike Vaughan
Carol Verrastro

CC: George Bennett
Pete Westermann

DATE February 14, 1994

FROM Steve Reardon

SUBJ DEA Security Issues

Attached, for your information and your DEA file, is a letter from Bill Reinig, DEA Diversion Security Specialist, to Diane Goyette, NWDA Director of Regulatory Affairs. The purpose of the letter is to summarize two security notices recently distributed to DEA field offices. One addressed a new GSA Class V specification for vault door construction; the other, controlled substance cage construction.

Evidently, as a result of the change in the GSA Class V vault door specifications, some local DEA offices were requiring vault doors of this new design. Reinig, in the letter, explains that while the GSA description did change, DEA regulations do not automatically require use of a GSA Class V door. Several different designs can meet DEA requirements. The cage construction section is self-explanatory.

If you have any questions, please call.

Attachment

Cardinal Health, Inc.
INTEROFFICE MEMORANDUM

To: Martin Alires/*Syracuse*
Bill Becker/*Florida*
Brendan Connolly/*Ellicott*
Mike Davison/*Behrens-Lubbock*
John Dewees/*Marmac*
Paul Exley/*Ohio Valley*
Jack George/*Behrens-Waco*
Ben Jones/*Chapman*
Les Killebrew/*Mississippi*
Harry Myers/*Humiston Keeling*
George Oughterson/*PRN*
John Roth/*Solomons*
Roy Stromski/*Daly*
Loren Todd/*Bailey*

CC: Joe Neary/*Whitmire*
Pete Westermann/*Dublin*

From: Steve Reardon *Steve*

Date: July 28, 1994

Re: **Order Forms (DEA Form 222)**

Attached for your information and your DEA file is a letter issued by DEA to further clarify their position on the proper completion of DEA Form 222 with respect to number of lines completed. The regulatory interpretation is as follows:

- When a purchaser has used five lines on a DEA Form 222 to order controlled substances, and two lines contain entries for the same product and package size, the number of items ordered would be four. If the purchaser erroneously indicated that five items had been ordered, DEA would deem this a minor error which could be corrected.

Please read the letter for the specifics of this interpretation and pass the information on to the appropriate personnel in your division.

If you have any questions, please call.

Attachment

Cardinal Health, Inc.
INTEROFFICE MEMORANDUM

To: Distribution

From: Steve Reardon, Joe Neary

Date: August 12, 1994

Re: **Reverse Management Systems (3CI) Waste Disposal Program**

Cardinal Health, Inc., has entered into an agreement with Reverse Management Systems (3CI) to dispose of our non-hazardous waste, including controlled substances, legend drugs, OTC items, and aerosols. Reverse Management Systems is registered with the Drug Enforcement Administration in Schedules II, III, IV and V, the Texas Department of Health, and the Texas Department of Public Safety. This registrant status allows them to receive and take possession of controlled substances and legend drugs for the purpose of disposal via incineration.

The pricing schedule is as follows:

1-24,999	pounds	$.045/lb.
25T-74,999	pounds	$.043/lb.
75T-99,999	pounds	$.041/lb.
> 100 T	pounds	$.039/lb.

The total pounds will be counted over a twelve-month period that will start with our first shipment. The steps to facilitate this process are outlined on the following page.

It is strongly recommended that this service be our sole method of disposal so that we may take advantage of volume discounts and assure compliance with applicable Federal, State, and local regulations. We believe that Reverse Management Systems (3CI) can provide us with a simple, efficient, and economical means to manage pharmaceutical waste. Please contact Joe Neary or me if, for some reason, you do not intend to utilize this service.

If you have any questions, please call.

Attachment

Cardinal Health, Inc.

PREPARING PRODUCT FOR DESTRUCTION

STEP ONE:

To arrange for destruction, contact:

Mr. Dennis Ingles, Operations Manager
Reverse Management Systems
DEA Number RE0196611
201 San Augustine Street
Center, Texas 75935

1-800 RX REVERSE (797-3837), or Fax 1-409-598-9539

STEP TWO:

Reverse Management Systems will provide you with DEA 222 Forms for your Schedule II products.

STEP THREE:

Create a debit memo or zero dollar invoice to Reverse Management Systems.
This will serve as documentation of the transfer and create required records (ARCOS, etc.).

STEP FOUR:

When preparing product for shipment:

1. Verify that each return is packed according to the products on the schedule II form.
2. Segregate, and package separately, all other schedules from the legend products.
3. Pack aerosols separately.
4. Note that legend and OTC product do not need to be packaged in any special order.
5. Notify Reverse Management Systems by telephone or fax as to when shipment will be made.
6. Attach an A.O.D. tag to the top of the box for all orders to be shipped UPS. All other shipments must have some other proof of delivery receipt.
7. Include a copy of the debit memo or invoice with the shipment.

STEP FIVE:

Upon completion of the products' incineration, you will receive the following receipts:

a) A copy of the completed DEA Form 41.
b) A detailed burn report, itemizing each box with third party verification.
c) An invoice detailing the amount based on per pound price.
d) Documentation showing the accurate weight and the actual destruction, by incineration date, verified by third party municipality.

CARDINAL HEALTH, INC.
MEMORANDUM

TO: Division Managers / Directors of Operation

FROM: Steve Reardon Steve

DATE: June 28, 1995

SUBJECT: Regulatory Reminder

CC: Michael Proulx
Joe Neary
Art Hammerschmidt
Carol Verrastro

When providing back-up delivery service to another division's customers there are licensing and record keeping issues that must be addressed in order to assure compliance with applicable regulatory requirements. These requirements are as follows:

LICENSING:

Transactions between divisions (except in Georgia and Ohio) qualify for an intra-company exemption, and state licensure is not required. Shipping prescription drugs and/or controlled substances direct to customers within a state requires licensure in most instances. The attached sheet identifies where Cardinal divisions are currently licensed and lists those states where out-of-state licensure is not required. This should assist you in identifying where to go for back-up.

RECORD KEEPING:

If you ship prescription drugs and/or controlled substances directly to another division's customer, your records (invoices, computer-generated sales history reports, ARCOS reports, etc.) must show that customer as the recipient of the product. The Prescription Drug Marketing Act (PDMA) and DEA regulations require wholesalers to maintain records of all transactions regarding the receipt and distribution of prescription and controlled drugs. These records must identify the "ship to" location.

We understand the importance of being able to provide this service to our customers. Our intention is not to restrict your ability to do so. Our purpose is to inform you of the regulatory requirements that must be met when doing so.

Joe Neary and I will work with our MIS groups to explore system support for the record keeping issues. In the interim, we are open to suggestions.

I hope this memorandum clearly identifies the issues at hand. If you have any questions or comments, please contact the Corporate Compliance Department at (614) 799-6050.

U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

SEP 14 1995

Ms. Diane Goyette
National Wholesale Druggists'
Association (NWDA)
Director of Regulatory Affairs
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

The Drug Enforcement Administration (DEA) is pleased to announce that the DEA Form 222 (U.S. Official Order Form - Schedule I and II) used to purchase controlled substances from DEA registrants has been changed for clarification purposes. The former line entitled " Number of Lines Completed" has been changed to " Last Line Completed".

This change was made as a result of requests made by DEA registrants to avoid confusion associated with the former requirement for an entry to be made for "number of lines completed". The new forms are already being distributed. Supplies of the old forms should continue to be used until they are depleted.

Please advise your membership of this change. We have enclosed a sample article which may be used for your publications. It is hoped that this change will obviate many problems associated with the former design of the form. If you have any further questions, please contact the Liaison and Policy Section at (202) 307-7297.

Sincerely,

G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

Enclosure

FOIA Confidential Treatment Requested By Cardinal

CAH SWE 019362

222 new wsk.wpd.

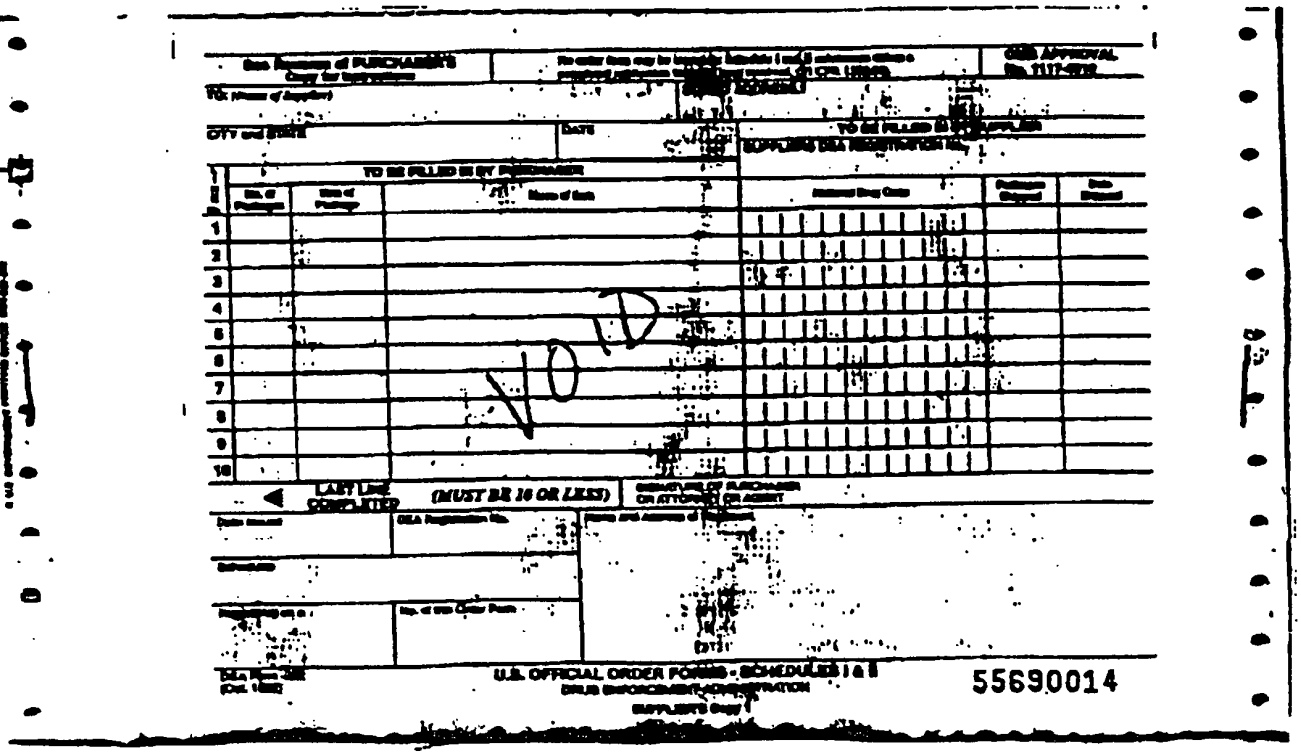
DEA CHANGES ORDER FORM (DEA-222)

The Drug Enforcement Administration (DEA) has announced that, at the request of registrants, a change has been made to the U.S. Official Order Form for Schedule I and II controlled substances (DEA-222). This change has been made for clarification purposes and involves the replacement of the line entitled "Number of Lines Completed" with " Last Line Completed".

The instructions pertaining to the change which appear on the reverse of each individual form indicate under item "8" the following: "Enter the last line completed - this generally should correspond to the number of lines used. If a number has not been entered, the form will be returned to you for completion before the supplier is allowed to fill it."

While DEA hopes that this clarification will eliminate much of the confusion the language of this part of the order form has caused some registrants over the years, they realize that errors will still occur due to misinterpretation. When it is clear to the supplier that the number of the last line completed has been incorrectly noted due to misinterpretation, rather than an attempt to facilitate diversion, the DEA form 222 should not be rejected.

The new clarified forms have already begun to be distributed although old forms should continue to be used until depleted.



See Reverse of PURCHASER'S Copy for Instructions

No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04).

OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)* CARDINAL
JAMES W. DALY, INC.

STREET ADDRESS
11 Centennial drive

CITY and STATE
Peabody, MA 01960

DATE
2/1/93

TO BE FILLED IN BY SUPPLIER
SUPPLIERS DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	1	500 ml	Methadone 10 mg/5 ml Oral Sol.			
2	6	100	MS Contin 60 mg Tablets			
3	5	10	Morphine Sulf. Inj. 250 mg			
4			Add-Vantage Vial 10 ml			
5	1	100	Ritalin 5 mg tablets			
6						
7						
8						
9						
10						

5 LAST LINE COMPLETED *(MUST BE 10 OR LESS)*

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT John Doe

Date Issued
11-25-92

DEA Registration No.
XXXXXXXXX

Schedules
2,2N,3,3N,4,5

Registered as a
Pharmacy

No. of this Order Form
987654321

Name and Address of Registrant

Your Pharmacy
100 Main Street
Anytown, USA 12345

DEA Form -222
(Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULE I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

46455319

FOIA Confidential Treatment Requested By Cardinal

CAH SWE 019364

U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

JUL 18 1996

Ms. Diane Goyette
Director of Regulatory Affairs
National Wholesale Druggists Association
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

Thank you for your letter of April 29, 1996, voicing your organization's satisfaction with the April 17, 1996 semi-annual meeting with your membership. I know I speak for all Drug Enforcement Administration (DEA) personnel present at that meeting, in conveying their appreciation for the information presented and the cooperation received.

There are several issues that have been long-standing and we would like to bring you up to date with current activities. The proposed rule on freight forwarding has cleared DEA and is ready to be forwarded to the Department of Justice (DOJ) and the Office of Management and Budget (OMB) for their approval. The DEA ARCOS Unit has resolved the problem of "inadvertent under-reporting" that was attributed to differences in National Drug Code Numbers (NDC) pertaining to sizes. The ARCOS Unit has been able to take care of this problem internally without any further involvement of ARCOS participants.

The last issue centers around delivery of Schedule II order forms by drivers and the associated distribution scenarios. DEA has carefully reviewed the scenarios discussed at the April 17, 1996, meeting and has approved the following circumstances in which driver handling of Schedule II Order Forms (DEA Form 222) will be permitted, and the circumstances under which we will allow DEA Forms 222 to be transmitted by facsimile. DEA will permit the driver to handle DEA Forms 222 provided they are carried in a sealed envelope. DEA will permit the "faxing" of DEA Forms 222 by the customer to the DEA registered distribution center, in order to facilitate the expedient filling of the DEA Form 222. The distributor may prepare the order

from the facsimile and then compare the prepared order with the controlled substances, when the original DEA Form 222s arrive with the driver. Under no circumstances will DEA permit the driver to have the sole responsibility for reconciliation of the pre-prepared order with the actual DEA Form 222. DEA also does not approve of the scenario that allows the driver to "fax" the copy of the order form at the cross-docking facility. The cross-docking facility should only be used for the temporary storage of controlled substances in transit and DEA will not recognize any other activity, such as "faxing", at the facility. Further, the driver should have no knowledge as to the contents of the DEA Form 222. Also, it is the opinion of DEA that allowing the drivers to be responsible for sole reconciliation of Schedule II orders does not provide the "special handling" of Schedule II orders that the Controlled Substances Act mandates and the diversion possibilities presented by this scenario are obviously more plentiful.

Please convey this decision to your membership. We will inform all of our field offices of this approved procedure, in the hope that it will prevent admonishments such as the one that one of your members was given for allowing the driver to transport the DEA Forms 222. As always, it was a pleasure meeting with you and your membership. If you have any questions, please contact the Liaison and Policy Section at (202) 307-7297.

Sincerely,

G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

AUG 28 1996

Ms. Diane Goyette
Director of Regulatory Affairs
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

Reference is made to our recent meeting regarding the facsimile transmission of DEA forms 222 from retail pharmacies to distributors. As I advised you at that time, the Drug Enforcement Administration (DEA) will permit the facsimile transmission of an executed DEA form 222 directly from a retail pharmacy to a distributor to facilitate filling of an order, provided that the facsimile copy is compared with the original copy prior to shipping the order. It is acceptable, although in our view, not desirable, to permit a proprietary driver, acting as an agent/employee of the distributor, to "fax" a DEA form 222 on behalf of the pharmacy, to the distribution center. The practice of allowing common or contract carriers to "fax" DEA forms 222 to distribution centers, however, is not in the public interest and does not effectively guard against diversion.

We realize that distribution centers adopted procedures for facsimile transmission of DEA forms 222 to expedite delivery of controlled substances to their customers. Nevertheless, we are very concerned that a practice that enables common or contract truck drivers, who are subject to only limited security checks and controls, to know exactly what a particular shipment of drugs will contain, poses a significant threat of diversion.

We urge your members, therefore, to cease this practice as soon as possible. It has been represented that the practice of "faxing" DEA forms 222 by common and contract carriers is widespread and well-established in many of your members' distribution centers. Therefore DEA will recognize a transition period until December 31, 1996 to discontinue this practice.

If you have any questions, please let me know.

Sincerely,

G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

U. S. Department of Justice

Drug Enforcement Administration
Office of Diversion

Washington, D.C. 20537

DEC 17 1997

Diane P. Goyette, Director
Regulatory Affairs
National Wholesale Druggists' Association
P.O. Box 2219
Reston, Virginia 20195-0219

Dear Ms. Goyette:

This is in response to your letter of August 13, 1997, regarding the proper procedure for documenting liquid controlled substance loss through accidental breakage of its container.

1. You ask whether such loss should be reported using a DEA Form-41, "Registrants Inventory of Drugs Surrendered," or a DEA Form-106, "Report of Theft or Loss of Controlled Substances."

When a bottle containing a controlled substance is accidentally broken, the registrant should report the loss on a DEA Form-41. The DEA Form-41 is used to report the disposal of controlled substances in the registrant's possession. As you are aware, DEA requires that the loss be reported in order to account for all dispositions of the controlled substance within the closed distribution system. Any remaining controlled substance, with the container labeling, should be disposed of in accordance with Title 21, Code of Federal Regulations (21 CFR), Section 1307.21. A registrant should use a DEA Form-106 to report an unaccounted for loss, a theft or a loss in transit.

2. You also ask what a distributor should use in the "Associated Registrant Number" and "DEA Order Form Number" fields of the ARCOS report.

The DEA *ARCOS Reporting Manual* states that the registrant, in accounting for the loss on an ARCOS report, should place a code "Y" in the transaction field, and the DEA Area Office Registration Number in the "Associated Registrant Number" field. The "DEA Order Form Number" field should remain blank.

3. And lastly, you inquire whether DEA requires a distributor to keep the pieces of broken bottle as evidence of the incident.

DEA does not require a registrant to keep the broken bottle pieces as evidence of the incident, but does require that the loss be documented as outlined above.

I trust that the foregoing adequately answers your questions. If we may be of further assistance, please do not hesitate to contact this office at (202) 307-7297.

Sincerely,

G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

Divisional Licensure By State

Alabama	Alaska	Arizona	Arkansas	California	Colorado
Calumet City Cord Logistics Jackson Knoxville Lakeland NSS-Albuquerque NSS-Nashville PharmPak Savannah	Auburn **Out of State Licensure Not Required**	Phoenix **Out of State Licensure Not Required**	Cord Logistics Jackson Kansas City Lakeland NSS-Albuquerque NSS-Nashville St. Louis Williams Drug	Auburn Calumet City Cord Logistics National PharmPak NSS-Nashville Ontario Sacramento Union City Valencia	Albuquerque Cord Logistics Denver Lakeland NSS-Nashville PharmPak Williams Drug

Connecticut	Delaware	Dist. of Col.	Florida	Georgia	Georgia cont'd.
Allentown Boston Cord Logistics Hartford Lakeland NSS-Albuquerque NSS-Nashville PharmPak Syracuse Williams Drug	Allentown Boston Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville Syracuse Williams Drug	Allentown Cord Logistics NSS-Albuquerque NSS-Nashville Wheeling	Calumet City Cord Logistics Jackson Knoxville Lakeland NSS-Nashville PharmPak Savannah Syracuse Williams Drug Winston-Salem	Auburn Boston Calumet City Cord Logistics Denver Knoxville NSS-Albuquerque NSS-Nashville PharmPak Phoenix Sacramento	Salt Lake City Savannah Waco Wheeling Winston-Salem Williams Drug

Hawaii	Idaho	Illinois	Indiana	Iowa	Kansas
Out of State Licensure Not Required	Auburn Cord Logistics Lakeland Salt Lake City Williams Drug NSS-Nashville	Calumet City Chicago Cord Logistics Kansas City Lakeland Milwaukee NSS-Albuquerque NSS-Nashville PharmPak St. Louis Williams Drug	Calumet City Chicago Cord Logistics NSS-Nashville PharmPak St. Louis Williams Drug	Calumet City Chicago Cord Logistics Kansas City Lakeland NSS-Albuquerque NSS-Nashville Minneapolis Williams Drug	Cord Logistics Kansas City Lakeland NSS-Nashville PharmPak Williams Drug

1

6/8/98

Divisional Licensure By State

Kentucky	Louisiana	Maine	Maryland	Massachusetts	Michigan
Out of State Licensure Not Required	Cord Logistics Jackson Knoxville Lakeland NSS-Albuquerque NSS-Nashville PharmPak Waco Williams Drug	Allentown Boston Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville PharmPak Syracuse Williams Drug	Allentown Boston Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville PharmPak Wheeling Williams Drug	Boston Out of State Licensure Not Required	Calumet City Chicago Cord Logistics Lakeland Milwaukee NSS-Albuquerque NSS-Nashville PharmPak Syracuse Williams Drug Zanesville
Minnesota	**Mississippi**	**Missouri**	**Missouri cont'd**	**Montana**	**Nebraska**
Calumet City Cord Logistics Lakeland Minneapolis NSS-Albuquerque NSS-Nashville PharmPak Williams Drug	Cord Logistics Jackson Knoxville Lakeland NSS-Albuquerque NSS-Nashville PharmPak Williams Drug	Auburn Chicago Cord Logistics Denver Houston Jackson Kansas City Knoxville Lakeland	NSS-Nashville Phoenix Sacramento Salt Lake City St. Louis Williams Drug Winston-Salem PharmPak	Auburn Cord Logistics Denver Lakeland NSS-Albuquerque NSS-Nashville Salt Lake City Williams Drug	Out of State Licensure Not Required
Nevada	**New Hampshire**	**New Jersey**	**New Mexico**	**New York**	**North Carolina**
Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville Phoenix Sacramento Salt Lake City Valencia Williams Drug	Allentown Boston Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville Williams Drug	Out of State Licensure Not Required	Albuquerque Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville Waco Pharmpak Williams Drug	Allentown Boston Cord Logistics Lakeland NSS-Nashville PharmPak Syracuse Williams Drug	Cord Logistics Knoxville Lakeland NSS-Albuquerque NSS-Nashville PharmPak Savannah Wheeling Williams Drug Winston-Salem

Divisional Licensure By State

North Dakota	Ohio	Ohio cont'd.	Oklahoma	Oregon	Pennsylvania
Cord Logistics Lakeland Minneapolis NSS-Albuquerque NSS-Nashville PharmPak Williams Drug	Auburn Boston Calumet City Cord Logistics Denver Jackson Knoxville Lakeland	NSS-Albuquerque NSS-Nashville PharmPak Phoenix Salt Lake City Syracuse Wheeling Williams Drug	Cord Logistics Kansas City Lakeland NSS-Albuquerque NSS-Nashville PharmPak Syracuse Waco Williams Drug	Auburn Cord Logistics NSS-Albuquerque NSS-Nashville PharmPak Salt Lake City Williams Drug	Allentown **Out of State Licensure Not Required**
Rhode Island	**South Carolina**	**South Dakota**	**Tennessee**	**Texas**	**Utah**
Allentown Boston Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville PharmPak Syracuse Williams Drug	**Out of State Licensure Not Required**	Cord Logistics Lakeland Minneapolis NSS-Nashville Williams Drug	Cord Logistics Jackson Knoxville Lakeland NSS-Albuquerque NSS-Nashville PharmPak St. Louis Syracuse Williams Drug	Albuquerque Boston Cord Logistics Houston NSS-Albuquerque NSS-Nashville PharmPak Waco Williams Drug	Salt Lake City **Out of State Licensure Not Required**
Vermont	**Virginia**	**Washington**	**West Virginia**	**Wisconsin**	**Wyoming**
Allentown Boston Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville	Allentown Cord Logistics Knoxville Lakeland NSS-Albuquerque NSS-Nashville Wheeling Winston-Salem Williams Drug	Auburn Cord Logistics NSS-Albuquerque NSS-Nashville PharmPak Spokane Williams Drug	Allentown Boston Cord Logistics Knoxville NSS-Albuquerque NSS-Nashville PharmPak Wheeling Williams Drug Winston-Salem	Calumet City Lakeland Milwaukee Minneapolis NSS-Albuquerque NSS-Nashville PharmPak Cord Logistics Williams Drug	Cord Logistics Denver NSS-Nashville Salt Lake City

6/8/98

Divisional Dis...oution By State

Alabama	Alaska	Arizona	Arkansas	California	Colorado
Cord Jackson Knoxville National PharmPak Savannah Williams Drug	Auburn Cord NSS-Nashville	Cord National PharmPak Nss-Nashville Phoenix Williams Drug	Cord Jackson Kansas City NSS-Nashville St. Louis Williams Drug	Auburn Cord National PharmPak NSS-Nashville Ontario Sacramento Union City Valencia Williams Drug	Albuquerque Cord Denver National PharmPak NSS-Nashville Williams Drug
Connecticut	**Delaware**	**Dist. of Col.**	**Florida**	**Georgia**	**Hawaii**
Allentown Boston Cord Hartford National PharmPak Williams Drug	Allentown Cord NSS-Nashville Williams Drug	Allentown Cord NSS-Nashville Wheeling	Cord Jackson Knoxville Lakeland National PharmPak NSS-Nashville Savannah Williams Drug	Cord Knoxville National PharmPak NSS-Nashville Savannah Williams Drug	Cord NSS-Nashville Ontario
Idaho	**Illinois**	**Indiana**	**Iowa**	**Kansas**	**Kentucky**
Auburn Cord NSS-Nashville Salt Lake City Williams Drug	Aurora Cord Kansas City Lombard Milwaukee National PharmPak NSS-Nashville St. Louis Williams Drug	Aurora Cord Lombard National PharmPak NSS-Nashville St. Louis	Aurora Cord Kansas City Lombard Minneapolis NSS-Nashville	Cord Kansas City National PharmPak NSS-Nashville Williams Drug	Cord Knoxville NSS-Nashville St. Louis Wheeling Williams Drug

7/14/98

1

Divisional Dis...oution By State

Louisiana	Maine	Maryland	Massachusetts	Michigan	Minnesota
Cord Jackson Knoxville National PharmPak NSS-Nashville Waco Williams Drug	Allentown Boston Cord Hartford National PharmPak NSS-Nashville Williams Drug	Allentown Cord National PharmPak NSS-Nashville Wheeling Williams Drug	Allentown Boston Cord Hartford National PharmPak NSS-Nashville Williams Drug	Aurora Cord Lombard Milwaukee National PharmPak NSS-Nashville Williams Drug	Cord National PharmPak NSS-Nashville Minneapolis Williams Drug
Mississippi	**Missouri**	**Montana**	**Nebraska**	**Nevada**	**New Hampshire**
Cord Jackson Knoxville National PharmPak NSS-Nashville Williams Drug	Cord Kansas City Lombard National PharmPak NSS-Nashville St. Louis Williams Drug	Cord Denver NSS-Nashville Salt Lake City Williams Drug	Cord Denver Kansas City National PharmPak NSS-Nashville	Cord NSS-Nashville Phoenix Sacramento Salt Lake City Valencia Williams Drug	Allentown Boston Cord Hartford NSS-Nashville Williams Drug
New Jersey	**New Mexico**	**New York**	**North Carolina**	**North Dakota**	**Ohio**
Allentown Boston Cord Hartford National PharmPak NSS-Nashville Williams Drug	Albuquerque Cord National PharmPak NSS-Nashville Waco Williams Drug	Allentown Boston Cord Hartford National PharmPak NSS-Nashville Williams Drug	Cord Knoxville National PharmPak NSS-Nashville Savannah Wheeling Winston-Salem Williams Drug	Cord Minneapolis NSS-Nashville Williams Drug	Aurora Cord Knoxville National PharmPak NSS-Nashville Wheeling Williams Drug

7/14/98

Divisional Dis_ _ution By State

Oklahoma	Oregon	Pennsylvania	Rhode Island	South Carolina	South Dakota
Cord Kansas City National PharmPak NSS-Nashville Waco Williams Drug	Auburn Cord National PharmPak NSS-Nashville Salt Lake City Williams Drug	Boston Cord National PharmPak NSS-Nashville Pennsylvania Syracuse Wheeling Williams Drug	Allentown Boston Cord Hartford National PharmPak NSS-Nashville	Cord NSS-Nashville Savannah Williams Drug Winston-Salem	Minneapolis NSS-Nashville Cord Williams Drug
Tennessee	**Texas**	**Utah**	**Vermont**	**Virginia**	**Washington**
Cord Jackson National PharmPak NSS-Nashville Williams Drug	Albuquerque Cord Houston National PharmPak NSS-Nashville Waco Williams Drug	Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug	Allentown Boston Cord Hartford NSS-Nashville	Allentown Cord Knoxville NSS-Nashville Wheeling Winston-Salem Williams Drug	Auburn Cord National PharmPak NSS-Nashville Spokane
West Virginia	**Wisconsin**	**Wyoming**			
Allentown Cord Knoxville National PharmPak NSS-Nashville Wheeling Williams Drug	Aurora Cord Milwaukee Minneapolis National PharmPak NSS-Nashville Williams Drug	Cord Denver NSS-Nashville Salt Lake City			

7/14/98

REQUIRED REPORTS TO DEA

Wholesalers are required to report regularly to DEA's ARCOS Unit all receipts and disposals of all Schedule I and II drugs and Schedule III narcotics. In addition, wholesalers are required to submit other reports to DEA under certain circumstances (e.g., drug thefts, drug destructions and suspicious orders).

ARCOS Reports

(21 CFR 1304.33)

Every wholesaler who handles controlled substances in Schedule I and II and/or narcotics in Schedule III must report to the ARCOS Unit, as follows:

When

Annual Inventory	To be taken on December 31
Initial Inventory	To be taken on the effective date that a substance becomes reportable
Transaction Reporting	Quarterly, or, with DEA permission, monthly

All reports are required to be submitted within 15 days after the end of the report period by certified or registered mail, return receipt requested.

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

Refer to The ARCOS Reporting Manual (Appendix A) for additional information.

Optional ARCOS Reporting Modes

Registrants using punched card accounting machines or electronic data processing equipment should submit either card decks or magnetic tapes. Registrants without automated systems must use the Manual ARCOS OCR Form - DEA Form 333 - (Form #9).

Reporting ARCOS Data from Another Location

For authorization to report ARCOS data from other than a registered location, a central reporting identified must be obtained from the ARCOS unit at the above address.

DEA Order Forms

(21 CFR 1305.09 (d))

Copy 2 (green) of the order form shall be sent to the local DEA office at the close of the month during which the order was filled. If the order is filled by partial shipments, Copy 2 (green) shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

Drug Thefts/Losses

(21 CFR 1301.74(c))

The registrant notifies the DEA field office in that area of any theft or significant loss upon discovery of such theft or loss on Report of Theft or Loss of Controlled Substances -DEA Form 106- (Form #10). Reports must be submitted within seven (7) days of the incident. Reporting in-transit losses is the supplier's responsibility. Reporting responsibility for shipments for which you have a signed receipt lies with the customer.

The reporting of inventory variances on DEA form 106 must be carefully evaluated. The most recent DEA policy addressing this issue reads as follows: "DEA regulations require a registrant to maintain inventory records to track the flow of controlled substances but do not require the maintenance of perpetual inventories. If a firm elects to regularly track inventory balances and notes a theoretical discrepancy, the firm should make every effort to resolve it within a timely manner. If it is determined that an actual discrepancy is the result of a theft or significant loss of controlled drug product, then the nearest DEA field office must be notified immediately upon discovery and the theft or loss must be reported on a DEA Form 106." Variances which are the result of record keeping or order filling errors need not be reported.

Any ARCOS reportable items filed on DEA Form 106 should also be submitted to ARCOS.

Note: Some state agencies require copies of all DEA Forms 106 filed with DEA.

Drug Destructions

(21 CFR 1307.21)

If a wholesaler wants to destroy certain controlled substances (e.g., damaged goods, returns, etc.), the wholesaler should notify the DEA special agent in charge on **Registrant Inventory of Drugs Surrendered - DEA Form 41 - (Form #11)** in triplicate. The special agent in charge will inform the wholesaler how the drug destruction will be handled. Where the wholesaler regularly disposes of controlled substances, the DEA special agent in charge can, upon request, authorize dispositions without prior approval provided that these dispositions are recorded fully and meet all conditions established by the special agent in charge. Destructions of reportable items must be submitted to ARCOS on **ARCOS OCR Form 333**.

> *Note: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.*

Cardinal has a contract with Reverse Management Systems to handle our destruction of unsaleable merchandise. The product is sold to Reverse Management Systems who in turn destroys it and files **DEA Form 41**. **Refer to DEA Correspondence 8/12/94 for additional information.**

DEA Form 41 should also be used for documenting a liquid controlled substance loss when the container accidently breaks. Any loss of an ARCOS reportable item must also be reported to ARCOS. The pieces of the broken bottle do not need to be retained as evidence of the accident. **Refer to DEA correspondence 11/17/97.**

Suspicious Orders

(21 CFR 1301.74(b))

Wholesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders. The wholesaler informs the DEA field office in that area of all suspicious orders. Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. DEA has no specific form for this.

Establishing Suspicious Order Criteria

Wholesalers should establish **written** criteria of what constitutes a suspicious order. DEA leaves it to the wholesaler to make this determination. The key for the wholesaler is to establish **reasonable** criteria based upon customer purchasing patterns and then to **adhere** to them in monitoring orders.

Either a computerized or a manual system can be utilized depending upon the wholesaler's preference and capability.

Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.

In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.

These charts should be posted in your cage and vault and the hospital and retail dosage limit quantities for particular items should be posted at the product locations.

Cardinal Health, Inc.

Anti-Diversion - Know Your Customer Compliance Manual

Table of Contents

CardinalHealth

I. KNOW YOUR CUSTOMER COMPLIANCE OVERVIEW

A. INTRODUCTION

This manual sets forth certain guidelines that Cardinal Health, Inc. ("Cardinal Health") has adopted in the United States to support various compliance policies, including the Anti-Diversion policy, the Secondary Market Sales policy, and the Internet Pharmacy policy (collectively, the "Know Your Customer Policies").

The Know Your Customer Policies are designed to facilitate salespeople knowing their customers and reporting any suspicious customer activities. Cardinal Health has set forth the procedures described in this manual as guidelines for all persons subject to the Know Your Customer Policies, including each of its officers and employees in the following positions or departments: operations management, finance management, chargebacks, credit management, and contracts (collectively, "employees"). Nothing in this manual is meant to alter or expand the requirements of the Know Your Customer Policies but instead is intended to provide guidance as to appropriate procedures to be utilized in implementing the Know Your Customer Policies' requirements.

The purpose of the Anti-Diversion policy is to detect and prevent the diversion of drugs that Cardinal Health sells to closed-door pharmacy customers at contract pricing. The Anti-Diversion policy further ensures compliance with applicable laws and regulations, contractual obligations and prevailing industry standards concerning the prevention of diversion.

The purpose of the Secondary Market Sales policy is to prevent Cardinal Health's customers from selling prescription pharmaceuticals purchased from Cardinal Health to other wholesalers. This is known as the "Secondary Market." The trading of prescription pharmaceuticals in the Secondary Market without a limit on the number of times a product is sold or a reliable record of prior sales can create opportunities for counterfeiters and price-diverters to introduce unreliable or price-diverted prescription pharmaceuticals into the Secondary Market.

The purpose of the Internet Pharmacy policy is to monitor the purchasing activity of internet pharmacies to which Cardinal Health sells prescription drugs to ensure that such pharmacies sell to individuals with proper prescriptions and comply with any applicable laws and regulations, contractual obligations, and prevailing industry standards concerning internet pharmacies.

Any questions about the Know Your Customer Policies or these guidelines or their applicability to a particular situation should be directed to a member of the Legal department or the Sales Compliance Coordinator (the "Compliance Coordinator").

B. UNDERSTANDING DIVERSION

It is the responsibility of every Cardinal Health employee whose job relates in any way to the sale of drugs at contract pricing or who interacts with accounts that purchase drugs at contract pricing to be able to understand and identify price "diversion."

CardinalHealth

The risk of price diversion primarily occurs in the context of sales by Cardinal Health to non-retail pharmacies that are contractually or otherwise legally restricted from reselling in the retail or wholesale market products purchased from Cardinal Health, including most typically pharmacies that purchase pharmaceuticals from Cardinal Health under manufacturers' contracts in order to service non-retail customers, such as nursing homes, hospitals, home care, and long term care facilities. These "closed-door" pharmacies are often entitled to purchase drugs from Cardinal Health at a reduced contract price under arrangements entered into by the pharmacy with the manufacturer (often through an intermediary called a "group purchasing organization"). To legitimately qualify for the contract pricing arrangements with the manufacturer, closed-door pharmacies are contractually required to use the products they purchase at the contract price for their "own use" in servicing the particular institutional or other non-retail populations they service. Nonetheless, in some instances, closed-door pharmacies may improperly "divert" product purchased at a contract price by reselling the drugs at a higher price on the open market in contravention of the "own use" requirement. This price "diversion" violates the contractual arrangement between the pharmacy and the manufacturer and may also violate federal and state laws.

When customers resell their product into the Secondary Market without any limit on the number of subsequent sales or a reliable record of sales that is sometimes also referred to as diversion. "Secondary Market" means the market for purchases, sales, or trades between wholesalers. Possible sales into the Secondary Market are addressed under Cardinal Health's Secondary Market Sales policy. The theft of pharmaceuticals and the resale into the Secondary Market can also be referred to as diversion. The risk of theft is addressed by various separate Cardinal Health policies, including the following SCS-P policies: DEA 00.00, 05.00, 06.01, 06.02, 06.03, 06.04, 07.00, 07.01, FDA 02.00, 08.00, 16.00, 16.01, and SCS-M QRA Policy 05 regarding security and anti-counterfeiting. All of these policies can be found on the mycardinalhealth.net website Home Page/Health Care Supply Chain Services/Businesses/Operations/Quality and Regulatory Affairs (Transportation and Warehouse Operations)/Document Library.

C. UNDERSTANDING THE RISKS OF IMPROPER SALES INTO THE SECONDARY MARKET

It is the responsibility of every Cardinal Health employee whose job relates in any way to the sale of prescription pharmaceuticals to customers that may resell into the Secondary Market to understand the risks associated with customers' sales into the Secondary Market without a limit on the number of subsequent sales or a reliable record of sales.

Sales by Cardinal Health to wholesalers or other customers that may resell those prescription pharmaceuticals to other wholesalers, re-packagers or anyone other than an end-user without any limit on the number of subsequent sales or a reliable record of sales may contribute to the inventory of prescription pharmaceuticals in the Secondary Market. The trading of prescription pharmaceuticals in the Secondary Market without a limit on the number of sales or a reliable record of prior sales can create opportunities for counterfeiters and price-diverters to introduce unreliable or price-diverted prescription pharmaceuticals into the mainstream distribution network. ***The Secondary Market Sales policy therefore forbids Cardinal Health customers from reselling product purchased from Cardinal Health to other wholesalers.***

CardinalHealth

D. UNDERSTANDING THE RISKS ASSOCIATED WITH INTERNET PHARMACIES

It is the responsibility of every Cardinal Health employee whose job relates in any way to the sales of prescription pharmaceuticals to pharmacies that operate websites where customers can order prescription drugs via the internet or supply prescription drugs to customers of other internet pharmacy websites to understand the risks associated with such internet pharmacies.

The sale of product to pharmacies that maintain websites can create a heightened risk that the internet pharmacy will intentionally or unintentionally sell prescription pharmaceuticals to individuals without proper prescriptions. Only prescriptions issued by a doctor acting in the usual course of professional practice are valid. If (a) the patient had a medical complaint, (b) the complaint resulted in a physical examination and discussion of medical history, and (c) a drug was prescribed shortly thereafter to relieve the condition, then the prescription is valid. Drugs dispensed pursuant to invalid prescriptions are considered diverted.

E. STANDARDS OF BUSINESS CONDUCT

One of Cardinal Health's most important assets is its reputation for integrity and honesty in dealing with customers, vendors, and regulatory entities. When Cardinal Health sells to customers that engage in diversion, Cardinal Health risks harming its reputation, impairing its relationships with manufacturers and regulators, and potentially incurring legal liability.

Accordingly, Cardinal Health expects that all of its employees will act in accordance with the Know Your Customer Policies to prevent and to report potential violations of the Anti-Diversion policy, Secondary Market Sales policy, or Internet Pharmacy policy. Each supervisor and manager is responsible for ensuring that the employees within his or her supervision are acting ethically and complying with applicable law and the Know Your Customer Policies. All present and new employees are responsible for reviewing the Know Your Customer Policies, for acquiring sufficient knowledge to recognize potential compliance issues applicable to their duties and for seeking advice regarding such issues when necessary.

All appropriate present and new employees will be provided copies of the Know Your Customer Policies and must acknowledge their receipt. A copy of the acknowledgment form is attached as Exhibit B.

F. REPORTING OF VIOLATIONS

Any employee who becomes aware of any diversion, suspected diversion, improper sales, or any violations of the Know Your Customer Policies must report that information to appropriate personnel at Cardinal Health in order that they may properly respond to the incident. Under this standard, employees are required to report any evidence of diversion or improper sales into the Secondary Market from which a reasonable person could conclude that there is more than an insubstantial risk that diversion or improper sales into the Secondary Market have occurred. Such a report must be made promptly in person, by phone, or in writing, to the Director of Operations at the distribution center servicing the account at issue as well as to one or more of the following:

CardinalHealth

a. Eric Brantley, Sales Compliance Coordinator, at (614) 757-5624;
b. Ivan Fong, Chief Legal Officer, or another attorney in the legal department; or
c. The Business Conduct Line at 800. 926.0834 inside of the United States or outside of the United States at the country specific telephone number listed on mycardinalhealth.net.

To the extent an employee is not comfortable being identified, the report may be made anonymously. Whether or not it turns out that improper acts did in fact occur, Cardinal Health will take reasonable precautions to maintain the confidentiality of employees who report, in good faith, illegal activity or violations of the Know Your Customer Policies, to the extent permitted by law. Cardinal Health will not discharge, demote, suspend, threaten, harass or, in any manner, retaliate against an employee who truthfully raises a concern about any actual or suspected violation. If an employee believes he or she has been retaliated against for providing such information, immediately contact the Ethics and Compliance, Human Resources or Legal departments or the Business Conduct Line.

If you have a question about whether particular acts or conduct may constitute diversion or violate the Know Your Customer Policies, you should contact one of the resources listed above. Employees who are in a supervisory capacity at Cardinal Health and who receive a report from a subordinate regarding suspected diversion or a violation of the Know Your Customer Policies have an independent obligation to ensure the incident is appropriately reported.

G. COOPERATION IN INVESTIGATIONS

Cardinal Health will promptly and thoroughly investigate reports of suspected diversions, improper sales into the Secondary Market, improper sales by internet pharmacies, or violations of the Know Your Customer Policies. Employees are required to cooperate fully with any investigation and not prevent, hinder, or delay the discovery and full investigation of suspected diversion or violations of the Know Your Customer Policies.

Except as provided below, no reprisals or disciplinary action will be taken or permitted against employees for good faith reporting of suspected diversion or violations of the Know Your Customer Policies or for cooperating in such investigations. Any retaliatory action in response to a good faith reporting of suspected diversion or violations of the Know Your Customer Policies or for cooperating in such investigations is prohibited.

H. DISCIPLINE FOR POLICY VIOLATIONS

Employees who participate in, enable, or condone diversion, or otherwise violate the Know Your Customer Policies, including by failing to report suspected diversion, possibly improper sales into the Secondary Market, or suspicious activity by internet pharmacies are subject to discipline up to and including dismissal. Employees who report their own improper conduct will have self-reporting taken into account in determining the appropriate disciplinary action.

I. EXTENT AND LIMITATIONS

Neither the Know Your Customer Policies nor these guidelines create a contract of employment between Cardinal Health and any Cardinal Health employee, nor does it alter the at-will employment

CardinalHealth

relationship or any employment contract and/or agreement between Cardinal Health and any Cardinal Health employee. Nor do they create an implied or express promise for specific treatment in specific situations. The Know Your Customer Policies and these guidelines are subject to change from time to time, and Cardinal Health reserves the right to terminate, amend or revise them at any time.

This manual does not address ethical or legal obligations beyond those pertaining to the Know Your Customer Policies. To the extent questions or issues arise concerning topics not covered here, employees should review the Cardinal Health *Standards of Business Conduct* which sets forth additional standards of integrity and responsible business conduct for Cardinal Health employees.

II. MISSION AND GOALS OF THE KNOW YOUR CUSTOMER POLICIES

Cardinal Health developed the Anti-Diversion policy to detect and prevent the diversion of the products it sells to its closed-door pharmacy customers at contract pricing. Cardinal Health developed the Secondary Market Sales policy to detect and prevent Cardinal Health customers from engaging in sales into the Secondary Market without a limit on the number of sales or a reliable record of prior sales. Cardinal Health developed the Internet Pharmacy policy to prevent improper sales by internet pharmacies to customers that may not be entitled to receive such drugs.

The mission of the Know Your Customer Policies is to facilitate salespeople knowing their customers and to maintain high ethical and legal standards with regard to the drug supply chain that Cardinal Health services. By demonstrating its commitment to this mission, Cardinal Health enhances value for its shareholders by maintaining Cardinal Health's reputation for excellence and integrity among its customers, vendors, and government regulators.

In support of the Know Your Customer Policies, Cardinal Health has implemented compliance requirements to meet the following goals:

- Screen new customers for potential diversion risks, the risk of re-selling prescription pharmaceuticals into the Secondary Market without a limit on the number of sales or a reliable record of prior sales, and the risk of selling prescription pharmaceuticals to individuals without proper prescriptions.
- Monitor Cardinal Health's sales to existing customers at contract prices for signs of diversion, sales to existing customers for signs of improper sales into the Secondary Market, and sales to internet pharmacy customers for signs of sales to persons without proper prescriptions.
- Educate and train employees regarding the identification of suspected diversion and other improper sales and the compliance requirements under the Know Your Customer Policies and these guidelines.
- Investigate instances of suspected diversion or other improper sales and respond appropriately based upon that investigation.
- Implement monitoring and reporting functions to measure the effectiveness of the Know Your Customer Policies and to address concerns in an efficient and timely manner.

CardinalHealth

- Establish enforcement and discipline mechanisms to ensure that all employees take their compliance responsibilities under the Know Your Customer Policies seriously.

III. SALES COMPLIANCE COORDINATOR JOB DESCRIPTION

The Compliance Coordinator for Cardinal Health, along with Supply Chain Service's Vice President of Quality and Regulatory Affairs and the Chief Ethics and Compliance Officer, is responsible for the administration of the Know Your Customer Policies. The responsibilities of the Compliance Coordinator shall include:

- Ensuring that Cardinal Health maintains procedures to effectively detect and prevent the diversion of products sold at contract pricing and other improper sales.
- Regularly reviewing the Know Your Customer Policies and these guidelines and recommending appropriate revisions and modifications to ensure that Cardinal Health complies with any legal requirements and prevailing industry standards regarding the detection and prevention of diversion or other improper sales.
- Coordinating resources to ensure the ongoing effectiveness of the Know Your Customer Policies.
- Overseeing retaliation-free report channels of suspected incidents of diversion or other violations of the Know Your Customer Policies.
- Assisting in the development of anti-diversion, secondary market sales, and internet pharmacy training and education programs for all appropriate Cardinal Health employees.
- Developing internal controls to detect instances or patterns of potentially illegal, unethical or improper conduct by Cardinal Health employees or its customers related to diversion or any violation of the Know Your Customer Policies.
- Developing and implementing appropriate procedures for the review and approval of new contract pricing customers, new wholesaler customers, and new internet pharmacy customers.
- Conducting or overseeing investigations of suspected diversion or violations of the Know Your Customer Policies and coordinating such investigations as appropriate with legal counsel.
- Recommending appropriate corrective action in response to demonstrated evidence of diversion or violations of the Know Your Customer Policies.
- Developing, coordinating and/or overseeing internal and external audit procedures for monitoring and detecting compliance with the Know Your Customer Policies.

The Compliance Coordinator is provided full authority by Senior Management to take all actions necessary to effectively implement these responsibilities. The Compliance Coordinator reports jointly to Pharmaceutical Distribution's Vice President of Quality and Regulatory Affairs and to Cardinal Health's Chief Ethics and Compliance Officer. In addition, the Compliance Coordinator

CardinalHealth

shall make reports on a regular basis to the Chief Ethics and Compliance Officer and Chief Legal Officer on matters related to his or her responsibilities. The Compliance Coordinator, at her or his discretion, may report issues to Senior Management and/or the Board of Directors.

IV. CUSTOMER SCREENING AND MONITORING PROCEDURES

A. INTRODUCTION

A crucial component of the Know Your Customer Policies involves reviewing customer relationships to identify evidence of potential diversion, sales into the Secondary Market without a limit on the number of sales or a reliable record of prior sales, or the sale of prescription pharmaceuticals to persons without proper prescriptions. This review occurs both through screening prospective customers prior to approval as a Cardinal Health account and through monitoring existing customers.

B. SCREENING POTENTIAL CUSTOMERS

Closed-Door Pharmacies

In addition to regular new account application requirement, certain new contract pricing customers must complete a Contract Pricing Declaration to provide information from which Cardinal Health can assess the risk of diversion. A copy of this form is attached as Exhibit C. On this form, the customer must identify: the basis for claiming contract eligibility; group purchasing organizations of which it is a member; affiliated retail pharmacies or wholesalers; other names it has operated under; patient or bed count information; and estimated sales. The customer is also asked to provide, when possible, the previous 3 to 12 months of drug utilization history. The Contract Pricing Declaration also contains a representation by the customer that it will not divert drugs purchased pursuant to an "own use" requirement and that such drugs will be utilized solely for lawful closed-door pharmacy business. The salesperson responsible for the prospective customer has the obligation to provide the Contract Pricing Declaration to the customer, and to assist the customer, if necessary, in submitting the proper information.

Certain customers who may have access to contract pricing are not required to sign a Contract Pricing Declaration. Those customers include:

- Hospitals
- Clinics (including 340B and PHS)
- Cardiac Catheterization Labs
- Physician offices
- Dentists
- Blood centers
- Dialysis clinics

CardinalHealth

- Surgery centers
- Home Health Care Agencies
- Infusion Centers
- Hospice
- Any other customer with access to contract pricing that solely dispenses drugs directly to the patient.

In addition to obtaining a completed Contract Pricing Declaration, the salesperson must visit the customer's site prior to the customer being approved in order to evaluate whether the customer's profile is accurate. This site visit must be documented using a Site Visit Form. A copy of this form is attached as Exhibit D. HSCS-P house accounts (i.e., an account that does not have a sales representative assigned to it) with average monthly sales less than $10,000 and HSCS-M ambulatory care accounts do not require a site visit, nor do certain national account sites, discussed in more detail below.

National alternate care chain accounts that have access to contract pricing (other than retail) are handled as follows:

- The parent must complete a Contract Pricing Declaration on behalf of all of its pharmacies. A list of all pharmacies owned and/or operated by the parent should be attached. The Contract Pricing Declaration must also indicate that the "own use" certification applies to all pharmacies serviced by the parent in the future.
- National Sales Administration will randomly select 5% of the national account's sites. The salesperson must visit these sites and complete a Site Visit Form. The remainder of those sites do not require an on-site visit for purposes of monitoring possible diversion.

In instances where a manufacturer requests pre-approval for customers who seek contract pricing, Cardinal Health will comply with those requests. In instances where manufacturers have not requested pre-approval, if the salesperson or corporate designee believes that pre-approval or consultation with the manufacturer would nonetheless be appropriate, such requests may be made after consultation with the Compliance Coordinator.

Before sales to the customer at contract pricing can begin, the Sales Manager (or Director) must review the Contract Pricing Declaration and Site Visit Form for evidence of potential diversion and sign off on the forms as a means of approving the customer. The original Contract Pricing Declaration, the Site Visit Form and the Sales Manager's (or Director's) approval must be kept in the customer's file in the primary servicing distribution center. Copies of the forms are also to be sent to the Compliance Coordinator.

Wholesalers

In addition to regular new account application requirements, each new wholesale customer must sign a Wholesaler Safe Product Practices certification and provide information from which Cardinal Health can assess the risk of diversion. A copy of the Wholesaler Safe Product Practices

CardinalHealth

certification is attached as Exhibit F. By signing this certification, the wholesale customer acknowledges its agreement to:

- not trade any prescription pharmaceutical product that is sold more than three times in the supply chain from the Manufacturer to the Final Dispenser
- put compliance measures in place to ensure the safety of the supply chain
- permit Cardinal Health to audit its compliance measures.

These Wholesaler Safe Practices are meant to ensure patients receive safe products in a timely manner. The salesperson responsible for the prospective customer has the obligation to provide the Wholesaler Safe Product Practices certification to the customer, to assist the customer, if necessary, in understanding and completing the certification, and to provide the completed certification to the Compliance Coordinator before shipping any pharmaceutical product to the wholesale customer. Cardinal Health may not ship any pharmaceutical product to any wholesale customer unless the customer has a valid and effective certification on file.

As part of the new customer set-up process, each potential new wholesale customer must provide certain information from which Cardinal Health can assess the risk of improper sales into the Secondary Market. This information includes any affiliated pharmacies or wholesalers, other names under which the wholesaler has operated, general information about its customers and expected purchases, and, when possible, the previous 3 to 12 month history of prescription pharmaceutical purchases.

Chain Pharmacy Warehouses

In addition to regular new account application requirements, each new chain pharmacy warehouse customer must provide usage information and evidence that shows that the warehouse is owned and/or operated by a group of affiliated retail pharmacies, or the parent company of such pharmacies.

The salesperson responsible for the prospective customer also has an obligation to obtain information about the business of the chain pharmacy warehouse customer from publicly available sources or commercially available third-party sources. In addition to being able to service the needs of our customer better, this type of due diligence will help Cardinal Health determine that the warehouse supplies prescription pharmaceuticals only to its affiliated retail pharmacies and/or individuals with prescriptions, and not to other wholesalers or unaffiliated buyers.

Internet Pharmacies

In addition to the new account application requirements, each new customer that operates a website where customers can order prescription drugs or supplies prescription drugs to customers of other internet pharmacy websites must be reviewed by the Compliance Coordinator before an account is opened.

CardinalHealth

The salesperson must also visit the customer's site prior to the customer being approved in order to evaluate whether the customer's profile is accurate. During the visit, the salesperson should document any evidence of a mail order operation at the pharmacy.

C. **MONITORING OF APPROVED CUSTOMERS**

Closed-Door Pharmacies

After a closed-door customer has been approved and sales at contract pricing have begun, Cardinal Health will monitor the customer for signs of suspected diversion. The Compliance Coordinator will be responsible for determining a monitoring protocol that may include the generation and review of reports from Cardinal Health's sales reporting systems, spot checks of randomly selected customers, and/or regular audits of customers based upon established parameters or profiles.

In addition to the initial site visit by the field salesperson, follow-up site visits should take place on at least an annual basis. Generally, the sales manager for the relevant region should conduct this site visit. A Site Visit Form should also be filled out for these reviews and maintained in the customer's file in the primary servicing distribution center.

Wholesalers

After a wholesale customer has been approved and sales have begun, Cardinal Health will monitor the customer for signs of suspected sales to other wholesalers, internet pharmacies, or anyone other than an end-user pharmacy. Annually, the Compliance Coordinator will visit each existing wholesaler customer's place of business. He will review randomly selected records, such as:

- purchase orders
- sales invoices
- compliance policies and procedures
- PDMA-relevant records
- Other data to ensure compliance with the certification

Upon the inspection, each wholesale customer must provide information such as any affiliated pharmacies or wholesalers, other names under which the wholesaler has operated, general information about its customers and expected purchases, and when possible, the previous 3 to 12 month history of prescription pharmaceutical purchases. If a wholesaler will not permit Cardinal Health to review these records, Cardinal Health will not ship any additional pharmaceutical product to this customer, and may take further action.

Chain Pharmacy Warehouses

After a chain pharmacy warehouse has been approved and sales have begun, Cardinal Health will exercise due diligence to determine that the chain pharmacy warehouse customer supplies prescription pharmaceuticals only to affiliated retail pharmacies and/or individuals with prescriptions. Cardinal Health will monitor sales to chain pharmacy warehouse customers and review information from publicly or commercially available third-party sources to look for indicia that the chain pharmacy

CardinalHealth

warehouse sells to entities other than affiliated retail pharmacies and/or individuals with prescriptions.

Internet Pharmacies

After an internet pharmacy has been approved, Cardinal Health will monitor the customer for signs of suspected diversion or sales to persons without proper prescriptions. Although no single factor will conclusively establish improper sales, some significant factors include whether the pharmacy accepts walk-in customers, the percentage of controlled substances purchases, and whether the pharmacy offers a wide range of products.

D. REPORTING

Suspected diversion or improper sales identified during the screening of potential customers or monitoring of an existing customer must be reported to the Compliance Coordinator.

Although no single factor will conclusively establish price diversion, some of the significant factors include:

- **Affiliations with Retail Pharmacies or Wholesalers.** A closed door pharmacy's affiliation with a non-closed door retail pharmacy or wholesaler may suggest the possibility of drugs being diverted through the affiliated operation.
- **Purchases Inconsistent with Business Model:** Purchases of product that is not generally prescribed for the type of populations serviced by the closed-door pharmacy (e.g., purchases of pediatric products by a pharmacy supplying nursing homes) or purchases in excess of volumes reasonably expected for the size of the population serviced by the pharmacy may be signs of diversion.
- **Purchases of Frequently Diverted Products**. Excessive purchases by a customer of certain drugs are warning signs of diversion. The Compliance Coordinator will maintain a list of such products.
- **Product Dating**. While some Cardinal Health customers require long product dating, product dating demands in excess of one year may suggest diversion.
- **Notification of Significant Denied Chargebacks**. Virtually all contract customers have chargebacks denied at some point. Nonetheless, chargeback denials from multiple manufacturers or denials related to frequently diverted drugs may be significant.
- **Significant Changes in Purchasing Patterns**. A striking and unexplained increase in the purchases of certain products may warrant further inquiry.
- **Notification by Manufacturers**. Manufacturers may request that Cardinal Health stop sales at contract pricing to certain customers due to excessive purchases of products by the customer. Such requests from multiple manufacturers may indicate diversion.

CardinalHealth

- **Purchases of Case Lot Quantities.** Repeated purchases of selected products in case lot quantities may be a sign of diversion.

- **Inquiries from Governmental Regulators:** Occasionally, Cardinal Health receives inquires from government regulators concerning particular customers. Those inquiries may sometime reflect suspected diversion on the part of the regulator.

Although no single factor will conclusively establish that a pharmacy is operating an illegal website or selling product into the Secondary Market, some of the significant factors include:

- **Purchases Inconsistent with Business Model:** Purchases of product that is not generally prescribed for the type of populations serviced by the pharmacy or purchases in excess of volumes reasonably expected for the size of the population serviced by the pharmacy may be signs of diversion.

- **Excessive Purchases of Controlled Ingredients or Substances.** Excessive purchases by a customer of controlled ingredients or substances can be warning signs of improper sales. The Compliance Coordinator will maintain a list of controlled ingredients and substances.

- **Significant Changes in Purchasing Patterns.** A striking and unexplained increase in the purchases of certain products may warrant further inquiry.

- **Affiliations with Closed Door Pharmacies, Internet Pharmacies, or Wholesalers:** Affiliations with closed-door pharmacies, internet pharmacies, or wholesalers may suggest the possibility of drugs being transferred improperly among the affiliates and sold in violation of a manufacturer's restrictions on resale or other regulations.

- **Inquiries from Governmental Regulators:** Occasionally, Cardinal Health receives inquires from government regulators concerning particular customers. Those inquiries may sometime reflect the regulator's suspicion that the customer is engaged in improper sales.

E. AUDITS

Cardinal Health's regular internal compliance audit reviews shall include tests for compliance with the reporting and recordkeeping requirements under the Know Your Customer Policies. In addition, the Compliance Coordinator may engage in random audits to ensure compliance with the Know Your Customer Policies, including with respect to whether the appropriate paperwork for a customer is on file and that any signs of potential diversion were appropriately identified and reported.

V. INVESTIGATION PROCEDURES

A. INTRODUCTION

An important component of the Know Your Customer Policies involves the investigation of suspected instances of diversion or other violations of the Know Your Customer Policies. The Compliance Coordinator is responsible for initiating and conducting such investigations and, in conjunction with the Chief Ethics and Compliance Officer, will oversee any appropriate corrective action.

CardinalHealth

B. PROCEDURE

The Compliance Coordinator may receive reports regarding suspected diversion, improper sales into the Secondary Market, or other violations of the Know Your Customer Policies from a number of different sources including his or her own monitoring efforts or a report from either an employee or a manufacturer. The Compliance Coordinator will conduct an initial assessment of each instance of suspected diversion or suspected violation of the Know Your Customer Policies to determine whether there is a reasonable risk that such activities did, in fact, occur. If the initial assessment suggests that diversion or a violation of the Know Your Customer Policies may have occurred, the Compliance Coordinator will undertake a further review and investigation. The Compliance Coordinator, in conjunction with Cardinal Health's Chief Ethics and Compliance Officer, will be responsible for directing the investigation and may engage outside counsel where appropriate to conduct the investigation. The Compliance Coordinator will begin the investigation as soon as reasonably practicable, but in no event more than thirty days after the Compliance Coordinator's initial receipt of the information that diversion was suspected.

Depending upon the circumstances of each case, the investigation may include any or all of the following components:

1. Collecting and reviewing the history of purchases by the customer;
2. Collecting and reviewing the customer's history of denied chargebacks;
3. Obtaining a corporate profile report for the customer identifying principles, affiliates, and other publicly available corporate information;
4. Obtaining a reverse directory report showing other business operating at the same address as the customer;
5. Confirming pharmacy and/or wholesale licensure for the customer and its affiliates;
6. Collecting and reviewing customer files maintained at the distribution center servicing the customer;
7. Interviewing the sales director, manager, and/or consultant responsible for the customer account; and
8. Where appropriate, requesting an explanation from the customer and/or conducting a site visit.

Within ten days of the conclusion of the investigation, the Compliance Coordinator will issue a report to Pharmaceutical Distribution's Vice President of Quality and Regulatory Affairs, with a copy to Cardinal Health's Chief Ethics and Compliance Officer with a judgment as to whether diversion has occurred and the recommended corrective action, which may include, as described in Section VI, contacting one or more relevant manufacturers, the appropriate GPO, ceasing sales to a given customer, or reporting the incident to appropriate governmental authorities.

CardinalHealth

The Compliance Coordinator will prepare and retain appropriate documentation of the investigation in accordance with Cardinal Health's document retention policies. Documentation should be maintained even if the investigation does not ultimately substantiate the initial report.

VI. CORRECTIVE ACTION

A. INTRODUCTION

If Cardinal Health discovers that one of its customers may have diverted product or otherwise violated the Know Your Customer Policies or that any of its employees may have facilitated diversion or otherwise failed to fulfill their obligations under the Know Your Customer Policies, Cardinal Health will take prompt corrective action. This may include corrective action both with respect to the customer or employee and, if necessary, more generally through revised policies and procedures.

B. CUSTOMER DIVERSION OR VIOLATION OF THE KNOW YOUR CUSTOMER POLICIES

If the Compliance Coordinator becomes aware of evidence demonstrating customer diversion or a violation of the Know Your Customer Policies, he or she will make a prompt report to Pharmaceutical Distribution's Vice President of Quality and Regulatory Affairs and the Chief Ethics and Compliance Officer, as described in Section V. At that time, the Chief Ethics and Compliance Officer will review the investigation report and approve in conjunction with the Legal Department and senior management as necessary, any appropriate corrective action. This corrective action shall take into account factors such as the following:

- The amount of diversion or improper sales;
- The length of time diversion or improper sales have occurred;
- Any prior incidents of suspected diversion, improper sales, or other concern involving the customer;
- The customer's response to the investigation, if relevant; and
- The manufacturer's response to the diversion or improper sales, if relevant.

The corrective action may include one or more of the following steps among others:

- Notifying the customer of the evidence of diversion or improper sales;
- Refusing to permit the customer to continue receiving contract pricing with respect to certain vendors or products;
- Notifying the manufacturer and/or GPO of the evidence of diversion or improper sales;
- Notifying appropriate governmental authorities in instances where Cardinal Health believes that there has been a clear violation of federal and/or state law; and

CardinalHealth

- Discontinuing business with the customer in instances where the problem is pervasive or the customer fails to take appropriate steps to prevent future incidents.

C. **EMPLOYEE VIOLATIONS**

Violations of the terms of the Know Your Customer Policies by any Cardinal Health employee, including a failure to report suspected diversion or improper sales, shall subject the employee to discipline, up to and including dismissal. Any reprimands will be placed in the employee's personnel file.

CardinalHealth

EXHIBITS

CardinalHealth

EXHIBIT A

Policy title

Anti-diversion

Policy statement

Cardinal Health, Inc., its divisions and majority-owned or controlled subsidiaries ("Cardinal Health") will establish procedures to detect and prevent the diversion of products that Cardinal Health sells to closed-door pharmacy customers at contract pricing.

All employees are responsible for following this policy and related procedures including, but not limited to reporting violations in accordance with the procedures. All officers, executives, managers and others with supervisory authority are responsible for implementing, enforcing, and following the policy and related procedures.

Definitions

A. "Diversion" includes any use or sale of a pharmaceutical product by a closed-door pharmacy that violates "own use" or other limitations imposed upon the pharmacy by law or as a condition of it receiving a discounted or contract price from a manufacturer or a group purchasing organization.

B "Closed-door pharmacy" means any non-retail pharmacy that is contractually or otherwise legally restricted from reselling in the retail or wholesale market pharmaceutical products purchased from the Company, such as a pharmacy that purchases pharmaceuticals under a manufacturer's contract in order to service non-retail customers, including nursing homes, hospitals, home care, or long term care facilities.

Scope

This policy applies to Cardinal Health, Inc., its divisions and majority-owned or controlled subsidiaries.

Effective date

01 November 2006

Responsible party

The Cardinal Health Chief Ethics and Compliance Officer is responsible for administering and amending this policy.

References

The following documents relate to this policy:

Title	Type
Establishment and application of Cardinal Health policies	Policy
Reporting obligations	Policy
Anti-diversion compliance manual	Procedure
Forms and additional information – anti-diversion	Resource Site
Standards of Business Conduct	Reference

CardinalHealth

EXHIBIT B

KNOW YOUR CUSTOMER POLICIES ACKNOWLEDGEMENT

I acknowledge that I have been provided with a copy of the Cardinal Health the Anti-Diversion policy, the Secondary Market Sales policy, and the Internet Pharmacy policy (collectively, the "Know Your Customer Policies"). I have read and understand the Know Your Customer Policies and agree to abide by their terms. I understand that a violation of the terms of the Know Your Customer Policies could subject me to discipline, up to and including dismissal.

_____

Cardinal Health Employee Name (Please print)

Date: _____

_____

Cardinal Health Employee signature

_____

Cardinal Health Employee title

Received by Human Resources Department:

_____

Date: _____

Uncontrolled copy if printed
Version 2

CardinalHealth

EXHIBIT C

CONTRACT PRICING DECLARATION

Signature of this declaration constitutes a representation that product received by you or your company from Cardinal Health Inc. at contract pricing will not be used in any manner that is inconsistent with limitations imposed upon you or your company by any contract or agreement with a pharmaceutical manufacturer or a group purchasing organization or by any state or federal law, including any applicable requirement that the product be used solely for your own use. Any violation of this declaration will constitute cause for immediate termination of your account.

Please provide the information requested below for each of your facilities. If there is more than one facility, please list all facilities on an attachment or fill out a separate form for each facility.

In addition, please attach any evidence of your Group Purchasing Organization affiliations and any manufacturer certifications evidencing your eligibility for contract pricing. Please also provide in electronic form data reflecting your last 12 months of pharmaceutical purchases.

Account Number: _____
Facility Name: _____
Address: _____
City: _____ State: _____
Telephone _____ Fax: _____
Other Names Which You Have Operated in the Last Year: _____
Parent Corporation (if applicable): _____
Any affiliates with retail and/or wholesale pharmacy licenses: _____
D.E.A. #: _____ HIN#: _____
Cardinal Health Division _____
Primary GPO: _____
Secondary GPOs: _____
Primary Business: _____
Patient/Bed Count: _____
Estimated Monthly Purchases: _____
Your Name: _____ Title _____
Signature: _____ Date: _____

Cardinal Health:

Sales Consultant/Manager Signature: _____ Date: _____
Sales Manager/Director Signature _____ Date: _____

Uncontrolled copy if printed
Version 2

CardinalHealth

EXHIBIT D

ALTERNATE SITE
CUSTOMER ON-SITE VISIT

Facility Name: _____
Address: _____
City: _____ State: _____ Ohio _____
Telephone _____ Fax: _____
D.E.A. #: _____ HIN#: _____

Cardinal Health Account #: _____

Cardinal Health Division: _____

Date of Visit: _____

Contact Person: _____ Title: _____

Was the Site consistent with the Customer Profile on the Contract Pricing Declaration? _____

If not, why? _____

Comments: _____

_____

Recommendation regarding Approval for Contract Pricing: _____

_____

_____ Date: _____
Sales Consultant/Manager Signature

_____ Date: _____
Sales Manager/Director Signature

Uncontrolled copy if printed
Version 2

FOIA Confidential Treatment Requested By Cardinal

CAH 014857

CardinalHealth

Policy title

Secondary Market Sales

Policy statement

The Brokerage, Parmed, and Distribution business units of SCS-P, the ambulatory care business unit of SCS-M, and Specialty Pharmaceutical Distribution ("Cardinal Health") will not sell prescription pharmaceuticals to Final Dispensers that resell those prescription pharmaceuticals into the Secondary Market. All Final Dispenser customers other than Chain Pharmacy Warehouses and government (or quasi-governmental) entities will be required to certify that they are Final Dispensers and that they do not and will not redistribute prescription pharmaceuticals purchased from Cardinal Health into the Secondary Market. This certification will be included in Cardinal Health's standard customer agreements and credit applications.

Sales to wholesalers.

Cardinal Health may sell prescription pharmaceutical products to a Wholesaler:

(a) that has executed the Wholesaler Safe Product Practices certification attached to this policy as Exhibit A; or

(b) under the following conditions set forth in the "Purchases and Sales due to Medical Emergencies, U.S. Government Requests or Manufacturer-Recognized Product Shortages" policy:

- when required by emergency medical needs reflect in any federal, state, or local government official's declaration, request, or statement;
- upon specific request from a Final Dispenser to treat a patient's emergency medical condition; or
- in the event of a manufacturer-recognized product shortage to satisfy legitimate Final Dispensers' needs.

Identifying new wholesale customers

The following procedures are designed to identify new Wholesaler customers, and will apply to all new customers:

(a) The credit application includes a question related to whether the customer is a wholesaler, as well as ownership interest questions designed to determine whether the customer is affiliated, directly or indirectly, with a wholesaler. The Credit Application is attached as Exhibit B.

(b) The sales consultant responsible for the account will research whether the customer has a state wholesale license in the customer's state of domicile and DEA wholesale license.

(c) Prior to making any sales of prescription pharmaceuticals to a new Wholesaler, the sales representative directly responsible for the account will obtain from the new Wholesaler customer:

(i) Information described in the Wholesale Customer Annual On-Site Verification Form attached to this Policy as Exhibit C; and

(ii) An executed Wholesaler Safe Product Practices certification. A copy of the certification will be maintained in the customer's file at the applicable distribution center, and a copy will be provided to the Vice President, Supply Chain Integrity and the Director, QRA.

Wholesaler customer audit program

Cardinal Health has created an audit program to verify the accuracy of the Wholesaler Safe Product Practices certification by its Wholesaler customers, as well as detect wholesaling activities by other customers (in excess of levels permitted by state law without a wholesale license).

(a) Annually, and upon identifying any information that calls the accuracy of a certification into question (including but not limited to, information reviewed in the reports described in subsection (c) below), Cardinal Health will conduct an on-site inspection of each of its certified Wholesalers. The Wholesaler

CardinalHealth

Policy title
Secondary Market Sales

Customer Assessment Form is attached to this policy as Exhibit D and includes an assessment of whether the Wholesaler has adequate security measures to protect against theft as well as other compliance measures designed to preserve the integrity of the pharmaceutical distribution chain.

(b) Annually, each sales representative directly responsible for accounts will obtain from existing Wholesaler customers:

(i) Information described in the Wholesale Customer Annual On-Site Verification Form.

(ii) A new Wholesaler Safe Product Practices certification.

(c) Cardinal Health will gather, monitor and analyze sales data to detect instances of possible sales of prescription pharmaceuticals into the Secondary Market by our customers. On a monthly basis, prescription pharmaceutical sales, in dollars, units and sales of frequently-diverted controlled substances, will be reviewed and analyzed to highlight abnormal transaction patterns, depending on the class of trade. This report will review all sales of prescription pharmaceuticals by HSCS-P.

(d) Cardinal Health will exercise due diligence to determine that each of its Chain Pharmacy Warehouse customers supplies prescription pharmaceuticals only to affiliated retail pharmacies and/or individuals with prescriptions.

Termination

Cardinal Health will terminate or sanction customers that are redistributing pharmaceuticals into the Secondary Market, are noncompliant with the Wholesaler Safe Product Practices certifications, or as to whom Cardinal Health obtains information indicative of unlawful activity. Such unlawful activity includes, but is not limited to, illegal internet pharmacy sales or price diversion. Please refer to Cardinal Health's policies entitled, "Internet Pharmacies: Customer Approval and Oversight Policy" and "Anti-Diversion", respectively, for more information regarding suspected unlawful activity.

Pedigree

Cardinal Health will pass appropriate pedigrees or pedigree information to all Wholesalers when and as required by any federal or state law.

Definitions

"Final Dispenser" means (i) entities and individuals, such as retail pharmacies, hospitals, physicians, and other authorized prescribers, whose practice with respect to prescription pharmaceuticals is devoted to dispensing or administering such pharmaceuticals to individual patients or patients' agents; (ii) chain pharmacy warehouses that exclusively supply retail pharmacies in their chains and/or individual patients with prescriptions; and (iii) entities that use prescription pharmaceuticals for research and development or clinical trials.

"Secondary Market" means the market for purchases, sales, or trades among Wholesalers.

"Wholesaler" means an entity that engages in the business of distributing prescription drugs to persons other than those with prescriptions or their agents, but does not include manufacturers or Final Dispensers.

Scope

This policy applies to Cardinal Health, Inc., its divisions and majority-owned or controlled subsidiaries in the United States.

CardinalHealth

Policy title

Secondary Market Sales

Effective date
1 January 2007

Responsible party
The Chief Ethics and Compliance Officer is responsible for administering and amending this policy.

References
The following documents relate to this policy:

Title	Type
Wholesaler safe product practices certification	Form
Credit application	Form
Wholesaler customer annual on-site verification	From
Wholesaler customer assessment	Form
Establishment and application of Cardinal Health policies	Policy
Anti-Diversion	Policy
Anti-Diversion Know Your Customer Compliance Manual	Procedure
Internet Pharmacy	Policy
Purchases and Sales Due to Medical Emergencies, U.S. Government Requests, Manufacturer-Recognized Product Shortages	Policy
Reporting obligations	Policy
Standards of Business Conduct	Reference
Forms and additional information – anti-diversion	Resource Site

CardinalHealth

EXHIBIT F

WHOLESALER
SAFE PRODUCT PRACTICES

To help thwart the counterfeiting and adulteration of pharmaceutical products and to suppress the illicit traffic in such products, [name of company] (the "Company") adopts the following practices:

1. Distribution Chain

The Company will not trade any prescription pharmaceutical product that is sold more than three times in the supply chain from the Manufacturer to the Final Dispenser.

a. Whenever the Company purchases any prescription pharmaceutical product from an entity other than a Manufacturer, it will:

i. purchase only from an Authorized Distributor of that Manufacturer or a wholesaler that has adopted these Wholesaler Safe Product Practices,

ii. if purchasing from an Authorized Distributor that has not adopted these Wholesaler Safe Product Practices, obtain a written certification from that Authorized Distributor that said product was purchased directly from the Manufacturer, and

iii. sell that product only to a Final Dispenser.

b. If the Company purchases a prescription pharmaceutical product from a Manufacturer, it will sell that product only to a Final Dispenser or to a wholesaler that has adopted these Wholesaler Safe Product Practices and within the last 12 months certified its compliance as required by paragraph 3.

c. The Company will provide purchasers with pedigrees or pedigree information when and as required by any federal or state law.

2. Compliance

a. The Company will have compliance measures, subject to audit by its trading partners or third parties, designed to detect and prevent (i) the purchase or sale of any prescription pharmaceutical that will be sold more than three times in the supply chain from the Manufacturer to the Final Dispenser; (ii) diversion of prescription pharmaceuticals, including sales by Closed-Door Pharmacies into the Secondary Market; and (iii) other practices impairing the integrity of the pharmaceutical distribution chain. The compliance measures shall include mechanisms for punishing or terminating employees and excluding trading partners who engage in such practices.

b. The Company will comply with the PDMA, any regulations in force thereunder, and any other applicable federal and state law governing wholesaling of prescription pharmaceuticals.

c. The Company will comply with HDMA Recommended Guidelines.

CardinalHealth

3. Certification

a. Upon adoption of these Wholesaler Safe Product Practices and at the end of each year thereafter, the Company will designate one of its officers who will certify the company's compliance with such Practices in the form annexed.

b. Upon request, the Company will provide the certification, via United States mail, to any federal, state or local governmental entity for retention in that entity's files, and for any use as such entity sees fit.

4. Verification

The Company will include an audit of its compliance provisions under paragraph 2 above in its annual audit plan.

5. Exceptions

a. If emergency medical needs require in particular instances that a prescription pharmaceutical be purchased from or sold to an entity other than as provided above, such purchase or sale does not violate these Wholesaler Safe Product Practices. Nor does it violate these Wholesaler Safe Product Practices to make de minimis sales to a wholesaler in the event of a manufacturer–recognized product shortage to satisfy legitimate Final Dispensers' needs.

b. If an agency of the United States government directs that particular prescription pharmaceuticals be purchased from an entity other than as provided above, then such purchase, for distribution only to such agency, does not violate these Wholesaler Safe Product Practices.

c. Sale of prescription pharmaceutical products to units of federal, state, or local government, for use by such governmental units, including medical facilities owned by governmental or quasi–governmental agencies, instrumentalities, or authorities, or for intragovernmental transfer for such use, does not violate these Wholesaler Safe Product Practices.

6. Definitions

The following definitions apply to terms used in these Wholesaler Safe Product Practices:

a. "Manufacturer" means an establishment authorized to engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, as reflected in a registration with the United States Food and Drug Administration, or an establishment that submits listing information directly to the Food and Drug Administration and obtains a Labeler Code.

b. "Authorized distributor" means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, as established by a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments.

c. "Final Dispenser" means (i) entities and individuals, such as retail pharmacies, hospitals, physicians, and other authorized prescribers, whose practice with respect to prescription pharmaceuticals is devoted to dispensing or administering such pharmaceuticals to individual patients or patients' agents; (ii) chain pharmacy warehouses that exclusively supply retail pharmacies in their chains and/or individual patients with prescriptions; and (iii) entities that use prescription pharmaceuticals for research and development or clinical trials. Accordingly, an entity is not a Final Dispenser if its business includes the sale of prescription pharmaceuticals to wholesalers.

d. A prescription pharmaceutical is "sold" each time it is the subject of any sale or transfer, except for transactions in which the purchaser or transferee, rather than subsequently dispensing or reselling the pharmaceutical, subsequently returns it in full compliance with federal and state law.

e. "PDMA" means the Prescription Drug Marketing Act, Public Law No. 100-293, 102 Stat. 95 (Apr. 22, 1988), as subsequently amended and codified.

f. "HDMA Recommended Guidelines" means the Healthcare Distribution Management Association's "Recommended Guidelines for Pharmaceutical Distribution Integrity" dated November 6, 2003, and available at www.healthcaredistribution.org, except that the guidelines shall be deemed to require vendor inspections on an annual basis.

Certification of Compliance with Wholesaler Safe Product Practices

Signature of this certification constitutes a representation that your Company complies with the annexed Wholesaler Safe Product Practices, as set forth more fully in the next paragraph. Any violation of those practices will constitute cause for immediate termination of your accounts with any vendors or customers.

I hereby certify that (i) the Company has adopted these Wholesaler Safe Product Practices and fully complied with them during the past 12 calendar months (or since the firm adopted these Wholesaler Safe Product Practices, if that period is shorter); (ii) that the Company will continue to comply with the Wholesale Safe Product Practices; (iii) that the Company makes this certification to induce entities to sell and/or to purchase prescription pharmaceutical products to and from it; and (iv) that I have made sufficient inquiry to be able to make the certification truthfully and accurately and without material omissions. The Company also agrees to permit Cardinal Health Inc. or its agents to perform audits to verify [name of company's] compliance with the Wholesaler Safe Product Practices. I understand that any false statements herein may violate federal or state laws and result in liability thereunder.

Your name:
Title:
Company Name:
Signature: _____
Date: _____

CardinalHealth

Policy title

Internet Pharmacy

Policy statement

Cardinal Health, Inc., its divisions and majority-owned or controlled subsidiaries ("Cardinal Health") will identify and monitor the purchasing activity of internet pharmacies it sells prescription drug product. The policy is intended to support compliance with any applicable laws and regulations, contractual obligations, and prevailing industry standards concerning internet pharmacies.

Customer Approval Procedures

In addition to regular new account application requirements, the following information must be obtained:

- Does the pharmacy operate a website where customers can order prescription drugs via the internet?
- Does the pharmacy supply prescription drugs to customers of other internet pharmacy websites?

If the answer is yes to one or both of the above, please consult with Compliance Coordinator prior to signing customer. The Compliance Coordinator will conduct further research of the potential customer.

In addition, the salesperson must visit the customer's site prior to the customer being approved in order to evaluate whether the customer's profile is accurate. During visit, salesperson should document any evidence of a mail-order operation at the pharmacy.

Oversight

After an internet pharmacy has been approved, Cardinal Health will monitor the customer for signs of suspected diversion. Although no single factor will conclusively establish diversion, some of the significant factors include:

- Does the pharmacy accept walk-in customers?
- What percentage of the pharmacy's drug purchases are controlled substances?
- Does the pharmacy purchase a wide range of products?
- Is the pharmacy ordering more than 3,000 dosage units of phentermine a month?
- Is the pharmacy ordering more than 5,000 dosage units of hydrocodone a month?
- Is the pharmacy ordering more than 5,000 dosage units of alprazolam a month?
- Does the pharmacy pick up orders rather than having them delivered?

Reporting obligations

Suspected diversion or mail-order activity identified during the screening of potential customers or monitoring of an existing customer must be reported to the Compliance Coordinator as well as the Business Conduct Line at 1.800.926.0834. Although no single factor will conclusively establish diversion, some of the significant factors include:

- Inquiries from Governmental Regulators: Occasionally, Cardinal Health receives inquiries from government regulators concerning particular customers. Those inquiries may sometime reflect suspected diversion on the part of the regulator; particularly controlled substances.
- Excessive Purchases: Ingredient Limit Reports are to be reviewed monthly by each division and the HSCS Quality and Regulatory Affairs anti-diversion group. Any excessive purchases of the above mentioned ingredients over the above mentioned allowable dosage units must be reported to the Compliance Coordinator.
- Significant Changes in Purchasing Patterns: A striking and unexplained increase in the purchases of certain products may warrant further inquiry.

CardinalHealth

Policy title

Internet Pharmacy

- Affiliations with Internet Pharmacies or Wholesalers: Affiliation with an internet pharmacy or wholesaler may suggest the possibility of drugs being diverted through the affiliated operation.

Investigations

The Compliance Coordinator may receive reports regarding suspected diversion from a number of different sources including his or her own monitoring efforts. The Compliance Coordinator will conduct an initial assessment of each instance of suspected diversion, and if the initial assessment suggests that diversion may have occurred, the Compliance Coordinator will undertake a further review and investigation. Depending on the circumstances of each case, the investigation may include any or all of the following components:

1. Collecting and reviewing the history of purchases by the customer;
2. Collecting and reviewing the history of excessive purchases of hydrocodone, alprazolam, and phentermine by the customer;
3. Confirming pharmacy and/or wholesale licensure for the customer and its affiliates;
4. Collecting and reviewing customer files maintained at the distribution center servicing the customer;
5. Interviewing the sales director, manager, and/or consultant responsible for the customer account;
6. Where appropriate, requesting an explanation from the customer and/or conducting a site visit; and
7. Checking the pharmacy website for appropriate information.

At the conclusion of the investigation, the Compliance Coordinator will issue a report to Cardinal Health's Vice President of Quality and Regulatory Affairs, with a judgment as to whether diversion has occurred and the recommended corrective action.

Scope

This policy applies to Cardinal Health, Inc., its divisions and majority-owned or controlled subsidiaries in the United States.

Effective date

13 April 2007

Responsible party

The Chief Ethics and Compliance Officer is responsible for administering and amending this policy.

References

The following documents relate to this policy:

Title	Type
Establishment and application of Cardinal Health policies	Policy
Anti-Diversion	Policy
Anti-Diversion Know Your Customer Compliance Manual	Procedure
Secondary Market Sales	Policy
Purchases and Sales Due to Medical Emergencies, U.S.	Policy

CardinalHealth

Policy title

Internet Pharmacy

Government Requests, Manufacturer-Recognized Product Shortages	
Reporting obligations	Policy
Standards of Business Conduct	Reference
Forms and additional information – anti-diversion	Resource Site

Standard Operating Procedures

—

Corporate Quality & Regulatory Compliance

CardinalHealth

Standard Operating Procedures

TABLE OF CONTENTS

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA00.00

TITLE: Controlled Substance Inventory

ISSUE DATE: 6-15-2006

PAGE: 1 of 5

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA00.00**
TITLE: Controlled Substance Inventory	**ISSUE DATE:** **PAGE:** 2 of 5

PURPOSE: To comply with DEA and Cardinal Health, Inc. physical inventory requirements and to provide an accurate accounting of all controlled substances on hand on a specific date.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1. Each facility shall conduct the following inventories:

   a.) Biennial

      i.) Performed every two years on a date selected by the company for all controlled substances on hand in live, morgue and brokerage.

   b.) Year-end ARCOS

      i.) Performed at the close of business on December 31st for all ARCOS reportable controlled substances on hand in live, morgue and brokerage.

      ii.) The inventory report shall be filed with the ARCOS Unit of the DEA by January 15th of the following year.

   c.) Monthly

      i.) Performed every month for all controlled substances on hand in live, morgue and brokerage.

   d.) Daily Movement

      i.) Performed every day for all controlled substances having movement the previous day.

e.) Newly Controlled Drugs

i.) Initial inventory of newly controlled drugs performed on the effective date of control by all facilities having the drug on hand.

2. All inventories, other than daily movement, shall include all controlled substances on hand as of the inventory date including brokerage, returns, damages and other drugs awaiting disposal.

3. The inventory record shall:

a.) Be maintained in written, typewritten, or printed form.

b.) Be signed by those taking the count.

c.) Include the date of the inventory and whether the inventory was taken as of the open or close of business.

d.) Biennial and year-end inventories must be witnessed.

4. Inventories of Schedule I and Schedule II substances must be separated from inventories for all other substances.

5. Inventories for Schedule III through V substances may be maintained separately from all other substances or in a readily retrievable manner.

6. For each controlled substance in finished form, the required inventories must contain:

a.) Name of the substance.

b.) Each finished form (e.g., 10 mg tablet or 10 mg concentration per fluid ounce or milliliter).

c.) Number of units or volume of each finished form in each commercial container (e.g., 100 tablet bottle or 3 milliliter vial).

d.) Number of commercial containers of each such finished form (e.g., four 100 tablet bottles or six 3 bottles or six 3 milliliter vials).

7. For controlled substance returns, damaged goods, or substances awaiting disposal the inventory must contain:

a.) Name of the substance.

b.) Total quantity of the substance to the nearest metric unit of weight or the total number of units of finished form.

c.) Reason for the substance being maintained by the registrant.

8. When conducting an inventory, the following steps shall be taken:

a.) Do not allow any product into or out of the area during the count or recount.

b.) Counts should be conducted from count sheet with the on hand quantities suppressed.

c.) Compare the inventory results with the current on hand balance of each item.

d.) Recount any out of balance item.

e.) Run audit report for any out of balance item.

f.) Research the error, checking for orders picked, but not invoiced, mispicks, etc.

g.) Make appropriate adjustments as errors causing variances are detected.

h.) The distribution center manager shall sign off on the count sheet that he/she has reviewed all exceptions and that variances have been explained.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA00.00**
TITLE: Controlled Substance Inventory	**ISSUE DATE:**
	PAGE: 5 of 5

i.) File DEA Form 106, on a timely basis per SOP DEA04.00, for any item that cannot be resolved. **(Reference Exhibit EA00.00 Guidelines for Reporting Controlled Drug Inventory Discrepancies)**

9. Inventory records must be retained for three years (or longer if mandated by State record keeping requirements) from the date the inventory was taken and must be available for DEA inspection at the registered location where the inventory was made.

Guidelines For Reporting Controlled Drug Inventory Discrepancies

DEA regulations require a registrant to report significant losses on DEA Form 106. The following are guidelines that may be used in determining if it is necessary to file a DEA Form 106 for ***significant*** controlled drug inventory discrepancies. A DEA Form 106 should be filed if:

1. The inventory variance is greater than 1% of the total activity for the item over a 180 day period.

2. A loss on a specific item each month results in a significant loss over a period of time.

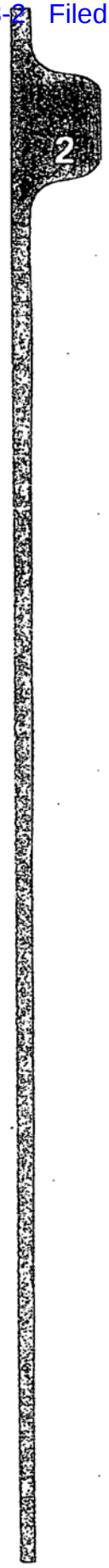
3. Losses of specific controlled substances that are likely candidates for diversion. DEA has identified the following as the most commonly diverted and abused Controlled pharmaceuticals:

- Hydrocodone (Lortab, Vicodin)
- Oxycodone (Oxy-Contin, Tylox, Percodan)
- Ketamine
- Hydromorphone (Dilaudid, Palladone)
- Cocaine
- Fentanyl (Actiq, Duragesic)
- Tramadol (Ultram)

4. A loss that is less than the 1%/180 day average but is deemed a significant quantity (i.e. full case, shelf pack).

NOTE: All lost-in-transit and thefts of controlled substances must be reported on DEA Form 106 regardless of the quantity of the loss.

Issued: May 5, 2005



CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:
DEA01.00

ISSUE DATE: 6-15-2006

TITLE: Verification of Customer DEA Registration Certificates and State Licenses

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA01.00**
TITLE: Verification of Customer DEA Registration Certificates and State Licenses	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To ensure customers are properly licensed through the Drug Enforcement Administration and the appropriate State licensing authority to purchase controlled substances and pharmaceutical products.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Each facility must maintain photocopies of the following for each customer:

a.) Valid and current DEA Certificate of Registration. **(Exhibit EA01.00)**.

b.) Valid and current State license.

2.) Customer registration and license expiration dates must be monitored on a monthly basis.

a.) The DEA Expiration Report shall be used for monthly monitoring. **(Exhibit EB01.00)**.

i.) Those accounts whose DEA registration or State license is due to expire shall be contacted either by letter or telephone, and shall be requested to provide an updated copy of their registration or license. **(Exhibits EC01.00, ED01.00, EE01.00)**.

3.) The Quarterly DEA Exception Report shall be reviewed on a quarterly basis to ensure sales of controlled substances are only made to current registrants. **(Exhibit EF01.00)**.

4.) When there is a reason to question a customer's registration or State license, or a copy is not available, the facility shall contact their local DEA office or the appropriate State licensing agency to ensure the customer is properly registered or licensed.

a.) Verbal contact with all regulatory agencies must be documented on a Regulatory Agency Contact Form. **(Form FA01.00)**.

5.) Controlled substance sales must be limited to only those authorized schedules listed on the customer's current DEA registration certificate.

6.) The facility must obtain new photocopies of the DEA Registration and State license for customers who relocate, reflecting their new business address.

a.) Orders must be shipped only to the location listed on the current certificate.

7.) When a change of pharmacy ownership occurs, and the new owner is continuing operations under the previous owner's DEA registration, the facility must obtain a signed Limited Power Of Attorney. (**Form FB01.00**).

a.) The 45-day limit imposed as part of the agreement must be monitored, after which time the new owner shall provide copies of their new DEA registration and State license.

b.) The signed Power Of Attorney shall be filed with the previous owner's DEA registration certificate.

NOTE: Reference DEA memorandum dated April 29, 1999.

EA01.00

CARDINAL HEALTH
11 CENTENNIAL DRIVE
P O BOX 6041

PEABODY MA 01960 - 0000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0108200	05-31-2007	PAID

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2, 3,3N,4,5	DISTRIBUTOR	04-25-2006

CARDINAL HEALTH
11 CENTENNIAL DRIVE
P O BOX 6041

PEABODY MA 01960-0000

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0108200	05-31-2007	PAID

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2, 3,3N,4,5	DISTRIBUTOR	04-25-2006

CARDINAL HEALTH
11 CENTENNIAL DRIVE
P O BOX 6041

PEABODY MA 01960-0000

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (7/05)

FOIA Confidential Treatment Requested By Cardinal

CAH 022032

EB01.00

1/31/03 15:52:23 QAR151

37 Cardinal Health - Auburn
DEA expiration report from 01/15/2003 to 02/15/2003 for State

PAGE: 1
AUBCUST501

Cust. Number	Customer Name	Street	City	St	Phone Number	DEA Number	DEA Expiration	State License	State Expiration
415021	2% LOWRYS PRESCRIPTIONS #2	10310 MERIDIAN AVE N	SEATTLE	WA	206 368 6060	BL7826487	1/20/2003	CP00057261	1/20/2003
415022	2% NORTHWEST PRESCRIPTIONS	1530 N. 115TH STE 112	SEATTLE	WA	206 365 2255	BM7826499	1/20/2003	CP00057262	1/20/2003

TOTAL LINE COUNT: 2

End of report . . .

1/31/03 37 Cardinal Health - Auburn PAGE: 1
15:52:52 DEA expiration report from 01/15/2003 to 02/15/2003 for DEA AUBCUSTS01
ORR151

Cust. Number	Customer Name	Street	City	St	Phone Number	DEA Number	DEA Expiration	State License	State Expiration
414748	CATALOG MEDICINE SHOPPE #0850	417 SOUTH TOWER	CENTRALIA	WA	360 736 4433	BM0925719	1/31/2003	CF00003081	6/01/2003
414491	FRED MEYER STORE #0165 RX	2655 SHASTA WAY	KLAMATH FALLS	OR	541 884 1780	BM0937473	1/31/2003	001026	3/31/2003
414264	INVERNESS JAIL(BOOKS) ONLY FLS)	11540 NE INVERNESS	PORTLAND	OR	503 988 5060	BM6950267	1/31/2003	001838	3/31/2003
414330	M MAFFETT'S GRANTS PASS PHCY	414 SW 6TH ST.	GRANTS PASS	OR	541 476 4262	AM5672755	1/31/2003	00225	5/15/2002
151047	MEDICAL OFFICE BLDG *ON ICE*	9155 SW BARNES RD	PORTLAND	OR	503 216 2630	AM9535658	1/31/2003	00770	3/31/2003
410846	MEDICINE SHOPPE #0261 PUYALLP	1210 EAST MAIN STREET	PUYALLUP	WA	253 848 1597	AM8029159	1/31/2003	CF00001875	6/01/2003
414253	MONROE FIRE DEPT.	163 VILLAGE COURT	MONROE	WA	360 794 7666	MM0256392	1/31/2003	1068	12/31/2005
411645	MURRAY DRUGS, INC.-HEPPNER	217 N MAIN	HEPPNER	OR	541 676 9158	AM1636882	1/31/2003	00242, 001459	3/31/2003
411644	MURRAY DRUGS, INC-CONDON	235 S MAIN STREET	CONDON	OR	541 384 2801	AM1620978	1/31/2003	00167	3/31/2003
411617	MWI DRUG	2105 51ST ST AVE S #203	FIFE	WA	253 926 6681	BM0222707	1/31/2003	FX00005474	10/01/2003
40784	ODESSA MEMORIAL HOSPITAL	502 EAST AMENDE DRIVE	ODESSA	WA	509 982 2611	AM9333214	1/31/2003	HF00001001	6/01/2003
414987	THE PHARMACY AT THE MOUNT	4831 35TH AVENUE SW	SEATTLE	WA	206 938 6196	BM4161559	1/31/2003	CF00004972	6/01/2003
415031	ZZ LOWRYS PRESCRIPTIONS #2	10330 MERIDIAN AVE N	SEATTLE	WA	206 368 6060	BL7826487	1/20/2003	CF00057263	1/20/2003
414779	ZZ MERCY MEDICAL CENTER INPT 2	2700 STEWART PARKWAY DRIVE	ROSEBURG	OR	541 677 2101	AM7527154	1/31/2003	00804	3/31/2003
414778	ZZ MERCY MEDICAL CTR INPT	2700 STEWART PARKWAY DRIVE	ROSEBURG	OR	541 677 2101	AM7527154	1/31/2003	00804	3/31/2003
415032	ZZ NORTHWEST PRESCRIPTIONS	1530 N. 115TH STE 112	SEATTLE	WA	206 365 2255	BN7826499	1/20/2003	CF00057262	1/20/2003

TOTAL LINE COUNT: 16

End of report . . .

1/31/03 15:53:02 ORR151

37 Cardinal Health - Auburn
DEA expiration report from 01/15/2003 to 02/15/2003 for Both

PAGE: 1
AUBCUST801

Cust. Number	Customer Name	Street	City	St	Phone Number	DEA Number	DEA Expiration	State License	State Expiration
414748	CATALOG MEDICINE SHOPPE #0850	417 SOUTH TOWER	CENTRALIA	WA	360 736 4433	BM0925719	1/31/2003	CF00003081	6/01/2003
414491	FRED MEYER STORE #0165 RX	2655 SHASTA WAY	KLAMATH FALLS	OR	541 884 1780	BM0937473	1/31/2003	001026	3/31/2003
414264	INVERNESS JAIL(BOXES ONLY PLS)	11540 NE INVERNESS	PORTLAND	OR	503 988 9060	BM6950287	1/31/2003	001838	3/31/2003
414130	M MAFFETT'S GRANTS PASS PHCY	414 SW 6TH ST.	GRANTS PASS	OR	541 476 4262	AM5672755	1/31/2003	00225	5/15/2002
181047	MEDICAL OFFICE BLDG -ON ICS-	9155 SW BARNES RD	PORTLAND	OR	503 216 2630	AM9535658	1/31/2003	00770	3/31/2003
410846	MEDICINE SHOPPE #0261 PUYALLP	1210 EAST MAIN STREET	PUYALLUP	WA	253 848 1597	AM8029159	1/31/2003	CP00001875	6/01/2003
414253	MONROE FIRE DEPT.	163 VILLAGE COURT	MONROE	WA	360 794 7666	MM0256192	1/31/2003	1068	12/31/2005
411645	MURRAY DRUGS, INC.-HEPPNER	217 N MAIN	HEPPNER	OR	541 676 9158	AM1636882	1/31/2003	00242, 001459	3/31/2003
411644	MURRAY DRUGS, INC-CONDON	235 S MAIN STREET	CONDON	OR	541 384 2801	AM1620978	1/31/2003	00167	3/31/2003
411617	MW1 DRUG	2105 51ST ST AVE S #203	FIFE	WA	253 926 6681	RM0222707	1/31/2003	FX00005474	10/01/2003
40784	ODESSA MEMORIAL HOSPITAL	502 EAST MENDS DRIVE	ODESSA	WA	509 982 2611	AM5333214	1/31/2003	HF00001001	6/01/2003
414987	THE PHARMACY AT THE MOUNT	4831 35TH AVENUE SW	SEATTLE	WA	206 938 6196	BM4161559	1/31/2003	CF00004972	6/01/2003
415031	ZZ LOWRYS PRESCRIPTIONS #2	10310 MERIDIAN AVE N	SEATTLE	WA	206 368 6060	BL7826487	1/20/2003	CF00057263	1/20/2003
414779	ZZ MERCY MEDICAL CENTER INPT 2	2700 STEWART PARKWAY DRIVE	ROSEBURG	OR	541 677 2101	AM7527154	1/31/2003	00804	3/31/2003
414778	ZZ MERCY MEDICAL CTR INPT	2700 STEWART PARKWAY DRIVE	ROSEBURG	OR	541 677 2101	AM7527154	1/31/2003	00804	3/31/2003
415032	ZZ NORTHWEST PRESCRIPTIONS	1530 N. 115TH STE 112	SEATTLE	WA	206 365 2255	BN7826499	1/20/2003	CF00057262	1/20/2003

TOTAL LINE COUNT: 16

End of report . . .

EC01.00

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
614.757.5000 main

CardinalHealth

www.cardinalhealth.com

DEAR VALUED CUSTOMER:

Federal and State regulations require wholesalers to maintain current records of their customer's licenses. A review of our records indicates that the following license will expire on the date shown.

**** DEA LICENSE EXPIRING ****
01/31/2003

Please send a **PHOTOCOPY** of your license(s) **A.S.A.P.** to enable us to continue shipments of CONTROLLED DRUGS to your account.

********** **PHOTOCOPIES REQUIRED** **********

OFFICE FAX # 253-833-9402
VAULT FAX # 253-833-9418

Thank you in advance for your prompt reply.

ED01.00

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
614.757.5000 main

CardinalHealth

www.cardinalhealth.com

DEAR VALUED CUSTOMER:

Federal and State regulations require wholesalers to maintain current records of their customer's licenses. A review of our records indicates that the following license will expire on the date shown.

**** STATE BOARD OF PHARMACY LICENSE EXPIRING ****
01/31/2003

Please send a **PHOTOCOPY** of your license(s) **A.S.A.P.** to enable us to continue shipments of LEGEND DRUGS to your account.

********** **PHOTOCOPIES REQUIRED** **********

OFFICE FAX # 253-833-9402
VAULT FAX # 253-833-9418

Thank you in advance for your prompt reply.

CARDINAL HEALTH
PHARMACEUTICAL DISTRIBUTION
801 "C" ST. NW SUITE B
AUBURN, WA 98001

*** DEA EXPIRATION NOTICE ***

Dear valued customer,

According to our records, your DEA registration will expire on 1/31/2003. In order that we may continue to process your controlled substance orders, please provide us with a copy of your renewed DEA registration. Your current DEA number is AM5333214

At this time, we are also requesting a copy of your current state license. Your current state license number is HF00001001
Please mail or fax your copy, with your customer numbers attached, to the attention of THE CUSTOMER SERVICE DEPT.
Fax Number: 1-253-833-9402

CUST#: 040784 303 - 020
ODESSA MEMORIAL HOSPITAL
502 EAST AMENDE DRIVE
ODESSA, WA 99159

EE01.00

EF01.00

CUDD820 CUSTOMER DEA EXCEPTION REPORT PAGE NO. 1
CARDINAL HLTH - SYRACUSE DATE 04/14/2006

CUST #	CUSTOMER	ADDRESS	CITY	ST	DEA NUMBER	DEA EXP. DATE
62122-8	TEST ACCOUNT- CARDINA	CARDINAL SYRACUSE	SYRACUSE	NY	AA1234567	01/31/2020
33648-7	ZZ SEVENTH DAY ADV NS	ROUTE 9 COLUMBIA COUN	LIVINGSTON	NY	AA6302044	06/30/2004
61001-4	MEDICINE SHOPPE TEST	12345 FIRST TRY AVENU	DUBLIN	OH	ABC12345	07/08/2005
62235-9	ZZ ONEIDA COUNTY HEAL	520 SENECA STREET	UTICA	NY	AB7468497	08/26/2005
01062-9	LEADER CHAIN CODE	203 JAMES ST.	CLAYTON	NY	AJ5917438	12/31/1999
62188-5	BERNE-KNOX-WESTERLO C	1772 HELDERBERG TRAIL	BERNE	NY	AK1536823	09/30/2005
62103-1	ZZ MERCY HOSPITAL OF	218 STONE STREET	WATERTOWN	NY	AM0564092	01/01/2003
62212-7	ZZ MERCY HOSP/DIALYSI	218 STONE STREET	WATERTOWN	NY	AM0564092	01/01/2003
01950-0	ZZ CVS #0039	75 WEST RT 59 SUITE 1	NANUET	NY	AM0564092	01/01/2003
01964-7	NEW YORK STATE ARTHUR	2911 ARTHUR KILL ROAD	STATEN ISLAND	NY	AN4164579	04/21/2005
62214-4	SUNY GENESEO	1 COLLEGE CIRCLE	GENESEO	NY	AN8322579	10/31/2003
40322-4	ZZ SHOP-RITE PRESCRIP	CLINTON & ROSSLER	CHEEKTOWAGA	NY	AP8148834	02/31/2003
01944-3	ZZ THOMAS ROBERT MD	215 WEST PENN STREET	LONG BEACH	NY	AS6627042	02/28/2003
62259-3	ZZ APEX THERAPEUTIC C	299 N. MAIN STREET, R	SPRING VALLEY	NY	AT0799001	11/30/2003
62298-2	BROOKDALERX INC.	1275 LINDEN BLVD	BROOKLYN	NY	BA8503713	09/30/2005
62298-3	BROOKDALE RX INC - 34	1275 LINDEN BLVD	BROOKLYN	NY	BB9177266	07/31/2008
62302-6	BROOKLYN/MCDONALD AVE	1080 MCDONALD AVENUE	BROOKLYN	NY	BB9177266	07/31/2008
62303-8	SHOPRITE RX DEPT #805	50-110 ROUTE 109	WEST BABYLON	NY	BB9284516	07/31/2008
62112-8	CAREMARK INC.	3250 MERIDIAN PARKWAY	FORT LAUDERDALE	FL	BB9361267	07/31/2008
62288-2	CVS # 1770	325 MAMARONECK AVE	WHITE PLAINS	NY	BC3454840	08/31/2001
62299-2	CAREMARK	1 GREAT VALLEY BOULEV	WILKES-BARRE	PA	BC9097189	12/31/2007
62294-6	COMMUNITY APOTHECARY,	5083 WESTERN TURNPIKE	DUANESBURG	NY	BC9180061	08/31/2007
62317-9	COMMUNITY APOTHECARY,	309 MAIN ST	SCHOHARIE	NY	BC9245994	06/12/2005
62308-4	CUSTOM LTC LLC	2322 MERRICK ROAD	MERRICK	NY	BC9245994	08/31/2008
62312-7	CURATIVE HEALTH SERVI	15 TECHNOLOGY PLACE	EAST SYRACUSE	NY	BC9431646	08/31/2008
62324-5	THE MEDICINE SHOPPE #	519 HOOPER ROAD	ENDWELL	NY	BC9478442	08/31/2008
62324-6	THE MEDICINE SHOPPE #	519 HOOPER ROAD	ENDWELL	NY	BC9593799	08/31/2008
62324-9	MEDICINE SHOPPE #1514	100 RANO BLVD.	ENDWELL	NY	BC9593799	08/31/2008
62325-0	MEDICINE SHOPPE #1514	100 RANO BLVD.	VESTAL	NY	BC9593802	08/31/2008
62324-7	MEDICINE SHOPPE #1518	8836 STATE RT 434	VESTAL	NY	BC9593802	08/31/2008
62324-8	MED SHOPPE #1518 GERI	8836 STATE RT 434	APALACHIN	NY	BC9593814	08/31/2008
62319-8	CVS #3105	9870 MAIN RD	APALACHIN	NY	BC9593814	08/31/2008
62324-3	THE MEDICINE SHOPPE #	1188 VESTAL AVENUE	MATTITUCK	NY	BC9609768	12/31/2007
62324-4	THE MEDICINE SHOPPE #	1188 VESTAL AVENUE	BINGHAMTON	NY	BC9628910	08/31/2008
62320-7	CVS # 01128	72 BROOKSIDE AVE	BINGHAMTON	NY	BC9628910	08/31/2008
62328-9	CVS #1030	280 SOUTH MAIN ST	CHESTER	NY	BC9632147	12/31/2007
62305-6	CALVIN DYSINGER, MD	1130 HIGHWAY 315	NEW CITY	NY	BC9691165	12/31/2006
62312-9	DVS PHARMACY INC.	460 MAMARONECK AVE	WILKES-BARRE	PA	BD9398822	06/30/2008
62317-4	ECHO DRUGS INC	260 BROADWAY	WHITE PLAINS	NY	BD9452727	06/30/2008
62288-1	CVS # 7881	97-15 METROPOLITAN AV	BROOKLYN	NY	BE9330008	08/31/2008
62292-6	FOUR CORNERS PHARMACY	340 DELAWARE AVENUE	FOREST HILLS	NY	BF9088255	12/31/2007
62289-5	CARESITE PHCY	21 COMMERCE COURT	DELMAR	NY	BF9110723	09/30/2007
62289-2	CARESITE PHARMACY	175 SOUTH WILKES-BARR	MOUNT POCONO	PA	BG9066956	09/30/2007
62289-1	CARESITE PHARMACY	1000 EAST MOUNTAIN DR	WILKES-BARRE	PA	BG9066970	09/30/2007
62289-3	SUREHEALTH LTC PHCY	119 MULBERRY STREET	WILKES BARRE	PA	BG9067009	09/30/2007
62288-9	CARESITE PHARMACY	125 SCRANTON POCONO H	SCRANTON	PA	BG9067047	09/30/2007
62317-2	GENESEE VALLEY GRP HL	899 MAIN ST	SCRANTON	PA	BG9067085	09/30/2007
62316-4	GENESEE VALLEY GRP HL	151 ELMVIEW AVE	BUFFALO	NY	BG9543213	09/30/2008
62316-7	GEISINGER SOUTH - WB	25 CHURCH STREET	HAMBURG	NY	BG9543225	09/30/2008
62318-0	GENESEE VALLEY GRP HL	1185 SWEETHOME ROAD	WILKES BARRE	PA	BG9547312	09/30/2008
			AMHERST	NY	BG9565269	09/30/2008

FOIA Confidential Treatment Requested By Cardinal

CAH 022039

FA01.00

CardinalHealth

REGULATORY AGENCY CONTACT FORM

1. _____ _____/_____
   Division Name Date Time

2. **Contact was made with:**
   - ❑ DEA Representative
   - ❑ State Board of Pharmacy Representative
   - ❑ FDA Representative
   - ❑ Other _____ (Please indicate agency)

3. **Contact was made by:**
   - ❑ Telephone
   - ❑ Visit at Division
   - ❑ Visit at Agency

4. **Contact initiated by:**
   - ❑ Division
   - ❑ Agency

5. **NAME, ADDRESS, AND TELEPHONE NUMBER OF REPRESENTATIVE**

   _____
   (Name) (Title)

   _____
   (Address) (Office working out of)

   _____
   (City) (State) (Zip)

6. **PURPOSE OF CONTACT (AUDIT, REQUESTING INFORMATION (include DEA's response), REPORTING SUSPICIOUS ORDERS, EXCESSIVE PURCHASES, ETC.)**

   _____
   _____
   _____
   _____
   _____

7. **IF INFORMATION OR RECORDS WERE PROVIDED, COMPLETE THE FOLLOWING:**
   - Information Sent: _____
   - Delivery Method: _____
   - Sent/Delivered By: _____

8. **FOLLOW-UP REQUIRED?** ❑ Yes ❑ No

9. **NAME OF EMPLOYEE COMPLETING THIS FORM:** _____

_____ _____
(Date) (Signed)

WHITE - Division YELLOW - Corporate Compliance

DUB 1301
Rev. 02/03

FOIA Confidential Treatment Requested By Cardinal

CAH 022040

FB01.00

LIMITED POWER OF ATTORNEY

_____ (Name of Registrant)
_____ (Address of Registrant)
_____
_____ (DEA Registration Number)

WHEREAS, (hereinafter referred to as "Seller") and (hereinafter referred to as "Buyer"), have executed a Purchase Agreement dated and related documents, all with the intent of transferring a pharmacy currently known as (the "Pharmacy") and

WHEREAS, the transfer referred to in said Purchase Agreement is to take place, or has taken place, on or about and

WHEREAS, the parties to the Purchase Agreement and this Power of Attorney desire that the business carried on at shall continue without interruption while BUYER obtains a DEA registration andthe varicus licenses necessary in the State of and until the transfers referred to in said Purchase Agreement take place; and

WHEREAS, such licenses are currently possessed by the Seller.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in the Purchase Agreement and related documents, and in an effort to implement the same, I, , who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents do make, constitute, and appoint , my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in accordance with Section 309 of the Controlled Substances Act (21 U.S.C. 828) and Part 305 or Title 21 of the Code of Federal Regulations for Pharmacy located at Such appointment shall authorize buyer to take all actions permitted by the undersigned pursuant to the aforesaid licenses, with respect to the management of the Pharmacy. I hereby ratify and confirm all that said Attorney-in-Fact shall lawfully do or cause to be done by virtue hereof; including the use of the DEA number of Seller until such time as a new DEA number and State pharmacy licenses are issued from the proper federal and state authorities.

IT IS FURTHER UNDERSTOOD that after the Closing Date in the Purchase Agreement, at such time as the undersigned no longer owns the assets of the pharmacy aforementioned, the operation of said pharmacy shall be solely in the control of Buyer and that nothing herein shall be construed so as to cause Buyer to be deemed the employee of the undersigned for any reason whatsoever, and that no action taken by Buyer shall give rise to any liability of the undersigned to any third party.

It is agreed by both parties that this appointment of Attorney-in-Fact shall terminate on the first to occur of Buyer obtaining all necessary licenses to operate the Pharmacy, or , 199 . (Power of Attorney cannot extend beyond 45 days of closing.)

By:_____

I, , accept the foregoing appointment, and I represent and warrant that I am a registered pharmacist, licensed to practice pharmacy in the State of , and I am the person named herein as Attorney-in-Fact and, that the signature affixed hereto is my signature.

By:_____

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA01.01

TITLE: Termination of DEA Registration Certificate and State Licenses

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA01.01**
TITLE: Termination of DEA Registration Certificate and State Licenses	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with DEA, State, and Cardinal Health, Inc. requirements for termination of regulatory licenses.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The distribution center must submit a registered or certified letter, return receipt requested, to their local DEA supervisor at least 14 days prior to closing the facility. The letter shall include the following information:

   a.) Name, address, registration number of distribution facility which is transferring the controlled substances and associated records and terminating the registration.

   b.) Name, address, registration number of distribution facility to whom the controlled substances and associated records will be transferred.

   c.) Date of the controlled substance transfer and a description of the proposed transfer procedure.

   d.) Date and time of termination.

2.) The distribution facility must contact the State licensing agency and follow their specific procedures for license termination.

3.) On the date of the transfer a complete inventory of all controlled substances being transferred must be conducted.

   a.) A copy of the inventory must be maintained with the records for each distribution facility.

4.) The transfer must be documented as a sale and purchase.

a. The following documents must be created:

i.) Purchase orders

ii.) Schedule II order forms (222's)

iii.) Invoices

iv.) Receiving documents

5.) The Corporate Compliance Department shall arrange and supervise the transfer of all controlled substances.

6.) Upon termination of the registration, the distribution facility must submit to their DEA office, via registered or certified mail, return receipt requested, a cover letter and the following:

a.) DEA Certificate of Registration

b.) Unused DEA Forms 222

7.) Upon termination of State licenses, the facility must submit to the proper licensing authority, via registered or certified mail, return receipt requested, a cover letter and the following:

a.) State license or permit

b.) Information requested by the State authority

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA02.00**
TITLE: Maintenance of Controlled Drug Records	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 5

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA02.00**
TITLE: Maintenance of Controlled Drug Records	**ISSUE DATE:** **PAGE:** 2 of 5

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for maintenance of controlled substance records.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Each distribution facility must maintain, on a current basis, a complete and accurate record of every controlled substance received, distributed or otherwise disposed. Each record shall contain:

a.) Name of the substance.

b.) Each finished form (e.g. 10mg tablet or 10mg concentration per fluid ounce or milliliter).

c.) Number of units or volume of each finished form in each commercial container (e.g. 100-tablet bottle or 3-milliliter vial).

d.) Number of commercial containers of each such finished form (e.g. four 100 tablet bottles or six 3 milliliter vials).

e.) Receiving records (vendor receipts, customer returns) must also contain:

i.) Actual date of receipt.

ii.) Name, address, and DEA registration number of the registrant from whom containers were received.

f.) Distribution records (sales, samples, vendor returns, third party vendor returns) must also contain:

i.) Actual date of distribution.

ii.) Name, address, and DEA registration number of the registrant to whom containers were distributed.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA02.00**
TITLE: Maintenance of Controlled Drug Records	**ISSUE DATE:** **PAGE:** 3 of 5

2.) A Schedule II order form (DEA Form 222) must be completed as part of the receiving and distribution record for Schedule I and II drugs.

3.) Separate records must be maintained for:

a.) Each registered location.

b.) Each registered activity (i.e. distributor, exporter).

c.) Schedule I and II drugs.

4.) Records for Schedule III through V transactions must be filed separately or must be readily retrievable if filed with other noncontrolled drug transactions.

5.) The distribution facility must notify the DEA special agent in charge of the field office covering their area if financial or shipping records will be maintained at a central location.

a.) The notification must contain:

i.) Name, address and registration number of location requesting permission.

ii.) Name, and exact address where central records will be kept.

iii.) A brief description of the records system (manual or computer-generated) and the records to be maintained centrally.

iv.) A statement agreeing to make the records available at the registered location within two business days.

b.) The notification must be sent:

i.) In triplicate.

ii.) Certified or registered mail, return receipt requested.

c.) The distribution facility shall proceed with the central records system if DEA does not respond within 14 days after the receipt by the special agent in charge.

d.) Inventories for all schedules of controlled drugs and executed Schedule II order forms must be maintained at the registered location.

6.) Records for drop shipments must be clearly marked as such and shall not be filed with records that document actual receipt or distribution of controlled substances.

7.) The following records shall be maintained in a secure, accessible manner for three years or longer if mandated by state record keeping requirements:

a.) Receiving documentation.

b.) Invoices

c.) Credit memos.

d.) Narcotic Sales Report.

e.) Narcotic Order Forms (DEA Form 222), brown and blue copies and related records.

f.) Monthly ARCOS reports.

g.) ARCOS Edit Error Report and submission.

h.) Count sheets from periodic inventories.

i.) Ingredient Limit Report.

j.) DEA Form 106.

k.) DEA Form 41.

l.) Return Receipt Requested forms for any mailings.

Cardinal Health **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA02.00**
TITLE: Maintenance of Controlled Drug Records	**ISSUE DATE:** **PAGE:** 5 of 5

m.) Debit Memos for Returns to Vendors.

n.) Year-End ARCOS Inventory.

o.) Biennial Inventory.

p.) Proofs of Delivery (POD's) (2 year retention).

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA02.01

TITLE: Controlled Substance Shipping Errors

ISSUE DATE: 6-5-2006

PAGE: 1 of 2

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA02.01**
TITLE: Controlled Substance Shipping Errors	**ISSUE DATE:** **PAGE:** 2 of 2

PURPOSE: To comply with DEA and Cardinal Health, Inc. record keeping and reporting requirements.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Shipping errors must be documented as normal transfers of controlled substances and include the following:

   a.) DEA Form 222 for Schedule I and II products.

   b.) Invoices.

   c.) Credit memos.

   d.) ARCOS reporting (as applicable).

2.) Each distribution and return shall be documented as a separate independent transaction.

3.) Shipping errors involving intra-company transfers shall be documented the same as customer shipments.

Reference: Exhibit EA02.01

Error Correction

In the following examples, assume the worst case --- the order was shipped to the customer. Also assume the shelf count confirms the error.

Although these examples only address shipping errors involving Schedule II controlled substances, certain portions of the corrective action processes also apply to shipping errors involving Schedule III-V controlled substances which must be handled in a similar fashion.

Example 1: A customer orders Ritalin 5mg 100. The order is keyed as Ritalin 10mg 100. The order filler picks Ritalin 10mg 100. **Customer receives and is invoiced for the wrong item.**

Corrective Action:

- Request the customer submit a blank for the mispicked item (Ritalin 10mg 100).
- Review the blank for accuracy, record the actual ship date, change the blank number in the ARCOS record. The blank number cannot be changed on the invoice.
- Key in the original blank with the correct item (Ritalin 5mg 100). Pick, bill, and ship the product. Attach a legible statement, preferably typed, to the original blank which reflects the correct NDC, ship quantity and date. Create an invoice and ARCOS record for the correct item.
- If the customer wants to return the mispicked item (Ritalin 10mg 100), issue a blank to the customer to buy back the product. Upon receipt, issue credit to the customer.

Example 2: A customer orders Ritalin 5mg 100. The order is keyed as Ritalin 5mg 100. The order filler picks Ritalin 10mg 100. **Customer gets wrong item, but is invoiced for the right item.**

Corrective Action:

- Have the customer submit a blank for the mispicked item (Ritalin 10mg 100).
- Review the blank for accuracy, record the actual ship date. Key in an order for the mispicked item (Ritalin 10mg 100), but do not ship the product. The customer will receive an invoice, but no product.
- Ship the correct product (Ritalin 5mg 100) from the original blank. The customer will get product, but no invoice.
- Change the ship dates of the products in the ARCOS records. The original invoice cannot be changed to reflect the actual ship date.

- If the customer wants to return the mispicked item (Ritalin 10mg 100), issue a blank to the customer to buy back the product. Upon receipt, issue credit to the customer.

Example 3: A customer orders 5xRitalin 5mg 100. The order is keyed as 10xRitalin 5mg 100. The order filler picks 10xRitalin 5mg 100. **Customer was billed for and received more than what he ordered.**

Corrective Action:

- Request the customer submit a blank for the additional product.
- Review the blank for accuracy, record actual ship date of product.
- Correct the ARCOS record to show correct ship quantity for original blank. The blank number and ship quantity cannot be changed on the invoice. Create another ARCOS record to show ship quantity, date, and blank number of overshipment.
- Correct the ship quantity on the original blank by drawing a line through the incorrect quantity and entering the correct quantity.
- If the customer wants to return the extra product, issue a blank to the customer. Upon receipt of the overshipment, issue credit to the customer.

Example 4: A customer orders 5xRitalin 5mg 100. The order is keyed as 5xRitalin 5mg 100. The order filler picks 10xRitalin 5mg 100. Customer received more than what he ordered or was billed.

Corrective Action:

- Request the customer submit a blank for the additional product.
- Review the blank for accuracy, record the actual ship date of the product.
- Key in an order for the overshipment, but do not ship product. Reference the actual ship date in the text field of the order.
- Modify the ARCOS record to show the correct ship date of the product.

Cardinal Health

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA02.02

TITLE: Brokerage Operations

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA02.02**
TITLE: Brokerage Operations	**ISSUE DATE:**
	PAGE: 2 of 3

PURPOSE: To comply with DEA, State and Cardinal Health, Inc. requirements related to brokerage controlled substance activity.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The distribution facility shall assume responsibility for all regulatory requirements as they apply to brokerage operations.

2.) Brokerage personnel must coordinate with distribution facility personnel to ensure they are following all facility procedures related to the receipt, distribution, storage, inventory, and record keeping requirements for controlled substances.

3.) All transaction records and reports for brokerage purchases, sales and other dispositions of controlled substances must be included in the distribution facility's records. (On the distrack system this is accomplished through a month end records transfer from the brokerage system to the facility's system.)

4.) Records for controlled substance transactions between brokerage and the facility must be deleted from the brokerage and facility record keeping systems.

5.) Brokerage controlled substance inventory must be stored in the cage or vault areas but shall be maintained separately from the facility's inventory and identified as brokerage inventory.

6.) Brokerage inventory must be included in all inventories conducted by the facility.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA02.02**
TITLE: Brokerage Operations	**ISSUE DATE:** **PAGE:** 3 of 3

7.) The distribution facility must obtain state licenses, as required, for those states into which they distribute to brokerage customers.

8.) The distribution facility must verify and maintain current copies of all brokerage customer DEA and state licenses.

Note: For more details on brokerage operations refer to the **Brokerage Warehouse Operations Manual** on file in your facility.

Cardinal Health **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.00**
TITLE: Narcotic Order Forms	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 5

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.00**
TITLE: Narcotic Order Forms	**ISSUE DATE:** **PAGE:** 2 of 5

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for obtaining, executing and storing narcotic forms.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) **A DEA Form 222 (Exhibit EA03.00)** must be executed for all transactions involving Schedule I and II substances.

   a.) Exceptions to the requirement must be approved by the DEA on a case-by-case basis.

   b.) Purchases from vendors and returns from customers must be executed on order forms issued by Cardinal Health Pharmaceutical Distribution.

   c.) Sales to customers must be executed on order forms issued by the customer.

2.) The following requirements must be followed when obtaining and executing order forms:

   a.) Only persons registered to handle Schedule I and/or II substances shall obtain order forms.

   b.) Order forms must be executed only on behalf of the registrant named on the order form.

      i.) Registrant must be currently registered to handle scheduled substances ordered.

   c.) When order forms are received from the DEA, the order form numbers shall be logged on the **DEA Narcotic Blank Log (Form FA03.00)**.

   d.) Order forms shall be kept in a secure location, pending use.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.00**
TITLE: Narcotic Order Forms	**ISSUE DATE:** **PAGE:** 3 of 5

3.) Each distribution facility shall follow these procedures for executing order forms for the purchase and return of Schedule I and II substances:

a.) Prepare and execute the form in triplicate.

b.) Use a typewriter, pen or indelible pencil.

c.) Enter only one item on each numbered line.

i.) Each item must be one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance.

d.) For each item, the form must show:

i.) Name of product ordered.

ii.) Finished or bulk form of product.

iii.) Number of units or volume in each commercial or bulk container.

iv.) The number of commercial or bulk containers ordered.

v.) The name and quantity per unit of the controlled substance or substances contained in the product if not in pure form.

vi.) Product catalogue number of the product, at the discretion of the purchaser.

e.) Enter the correct name and address of the supplier from whom the controlled substances are being ordered.

i.) Only one supplier may be listed on any one form.

f.) Enter the last line completed on the form.

i.) The number must correspond to the number of lines used.

ii.) If two lines are used on an order form to describe one item, the number of lines completed is two.

g.) Enter the execution date on the form.

h.) Sign the form.

i.) Signature must be that of a person authorized to sign a requisition for order forms on behalf of the purchaser.

4.) Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form.

a.) Unexecuted forms must be delivered promptly to the registered location upon an inspection of such location by an officer authorized to make inspection or to enforce any federal, state or local law regarding controlled substances.

5.) Completed order forms must be maintained as follows:

a.) The purchaser shall retain at the registered location printed on the order form:

i.) Copy 3 (blue) of each filled order form

ii.) All copies of each unaccepted or defective order form and statements attached to them

b.) The supplier shall retain copy 1 (brown) of each order form that has been filled.

c.) Copy 2 (green) must be sent to the local DEA office at the close of each month. (Refer to SOP DEA04.00)

6.) Order forms must be maintained separately from all other records.

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.00**
TITLE: Narcotic Order Forms	**ISSUE DATE:**
	PAGE: 5 of 5

7.) Order forms must be maintained for three years.

a.) State record keeping requirements may be more than three years and records shall be maintained accordingly.

8.) The previous day's Narcotic Order Forms must be reviewed for compliance with DEA regulations.

a.) A **Narcotic Order Review Form (Form FB03.00)** shall be completed for any order forms processed outside of the requirements of applicable Cardinal Health policy and procedure.

b.) Discrepancies and appropriate responsive action shall be discussed with personnel involved. The manager and employee shall sign the **Narcotic Order Review Form**.

c.) The Narcotic Order Review Form shall be filed with a copy of the corresponding DEA Form 222.

9.) All unused order forms for controlled substances listed in Schedules I and II shall be returned to the nearest DEA office via registered or certified mail, return receipt requested, in the event that the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address shown on the registration), or is suspended or revoked.

FA03.00

DEA NARCOTIC BLANK LOG AUBURN

DATE BLANKS REC'D BY DIVISION	BLANK NUMBER	HELD BY DIVISION	SENT TO PURCHASING	PO/MRA NUMBER	DATE BLANK USED	VENDOR / CUSTOMER NAME	DATE PRODUCT RECEIVED
01/07/03	21144451		X				
01/07/03	21144452		X				
01/07/03	21144453		X				
01/07/03	21144454		X				
01/07/03	21144455		X				
01/07/03	21144456		X				
01/07/03	21144457		X				
01/07/03	21144458		X				
01/07/03	21144459		X				
01/07/03	21144460		X				
01/07/03	21144461		X				
01/07/03	21144462		X				
01/07/03	21144463		X				
01/07/03	21144464		X				
01/07/03	21144465		X				
01/07/03	21144466		X				
01/07/03	21144467		X				
01/07/03	21144468		X				
01/07/03	21144469		X				
01/07/03	21144470		X				
01/07/03	21144471		X				
01/07/03	21144472		X				
01/07/03	21144473		X				
01/07/03	21144474		X				
01/07/03	21144475		X				
01/07/03	21144476		X				
01/07/03	21144477		X				
01/07/03	21144478		X				
01/07/03	21144479		X				
01/07/03	21144480		X				
01/07/03	21144481		X				
01/07/03	21144482		X				
01/07/03	21144483		X				
01/07/03	21144484		X				
01/07/03	21144485		X				

FB03.00

CardinalHealth

NARCOTIC ORDER REVIEW FORM

During a routine review of customer DEA Forms 222, order form number _____ (copy attached) was found to be filled in violation of DEA regulations.

The omission and/or error is indicated below:

_____ Order Form Not Written in Ink or Not Signed

_____ Customer/Registration Number: Unable to I.D. or Altered

_____ 60 Day Lapse from Date of Execution

_____ Item: Unable to I.D. or Altered

_____ Size, Number of Packages or Strength Altered, Incorrect or Omitted

_____ Strength Dittoed

_____ NDC #, Strength or Dosage Form Incorrect

_____ " Lines Completed" Box Not Filled In

_____ "Lines Completed" Box Altered

_____ Lines Completed Less than Lines Actually Ordered

_____ Our Name and Address or Date Omitted

_____ Item Discontinued or Not a Schedule II

_____ Customer Voided a Line

The resulting action should have been:

Void entire order form _____

Void single line _____

Fill in omission _____

Appropriate personnel have been reminded of the regulatory requirements regarding the filling of order forms that have not been properly prepared.

_____ Manager Signature

_____ Employee Signature

_____ Date

_____ Date

Revised 3/03

FOIA Confidential Treatment Requested By Cardinal

CAH 022066

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.01**
TITLE: Centralized Purchasing of Schedule II Drugs	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 3
RESPONSIBILITIES:	
APPROVALS: **Approved by:** _____ **Date:** 6-5-06 Stephen J. Reardon Vice President, Quality & Regulatory Affairs	

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.01**
TITLE: Centralized Purchasing of Schedule II Drugs	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for centralized purchasing of Schedule II Drugs.

SCOPE: Pharmaceutical Distribution facilities, P.D. Purchasing

POLICY:

1.) When the ordering of Schedule II drugs and the processing of the DEA Forms 222 is handled by Corporate Purchasing, the following steps shall be taken:

a.) Corporate Purchasing shall order DEA Form 222's by either:

i.) Contacting the appropriate DEA office or the DEA Registration Unit in Washington, D.C.

ii.) Completing a 222 Requisition Form.

b.) All 222 Requisition Forms received by the facility shall be forwarded to Corporate Purchasing.

c.) As Order Forms are received at the facility, the facility shall:

i.) Log the order form numbers onto the **DEA Narcotic Blank Log (Form FA03.01)**.

ii.) Retain an adequate supply of order forms for emergency purchases and customer return buybacks.

iii.) Forward remainder of order forms to Corporate Purchasing, along with a copy of the **DEA Narcotic Blank Log**.

iv.) If any order forms are missing the division shall notify the DEA per SOP DEA 03.09.

d.) Corporate Purchasing shall receive, log and store order forms in a secure place.

e.) Corporate Purchasing shall contact the facility if numbers are out of sequence or an order form is missing.

f.) Corporate Purchasing shall create a Schedule II purchase order and complete an order form.

g.) Corporate Purchasing shall copy the order form for purchasing records.

h.) Corporate Purchasing shall mail:

i.) Copy 1 (brown) and Copy 2 (green) copies of the order form to the vendor.

ii.) Copy 3 (blue) to the facility.

iii.) All three copies of voided order forms to the facility.

i.) Corporate Purchasing shall add order form number to purchase order.

j.) Corporate Purchasing shall transmit purchase order file to facility.

k.) As Copy 3 (blue) copies of order forms are received, the facility shall record appropriate information onto **DEA Narcotic Blank Log** and forward to appropriate personnel pending receipt of the product.

l.) Facility shall contact Corporate Purchasing if numbers are out of sequence or an order form is missing.

FA03.01

Revised 3/03

DEA NARCOTIC BLANK LOG

CardinalHealth

DATE BLANKS REC'D BY DIVISION	BLANK NUMBER	HELD BY DIVISION	SENT TO PURCHASING	PO/MRA NUMBER	DATE BLANK USED	VENDOR / CUSTOMER NAME	DATE PRODUCT RECEIVED

FOIA Confidential Treatment Requested By Cardinal

CAH 022070

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.02**
TITLE: Power of Attorney	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 3
RESPONSIBILITIES:	
APPROVALS:	

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.02**
TITLE: Power of Attorney	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for obtaining and revoking Power of Attorney.

SCOPE: Pharmaceutical Distribution facilities, P.D. Purchasing

POLICY:

1.) To authorize one or more individuals, whether or not located at the registered location, to obtain and execute order forms, each distribution facility shall:

a.) Contact Corporate Compliance to execute a **Power of Attorney (Form FA03.02)** for each individual.

b.) The Power of Attorney shall be signed by:

i.) The same person who signed or was authorized to sign the most recent application for registration or re-registration; and

ii.) The individual being authorized to obtain and execute order forms.

c.) File the power of attorney with the executed order forms of the purchaser.

d.) Retain the power of attorney for the same period as any order form bearing the signature of the attorney.

e.) Ensure that the power of attorney is available for inspection together with other order form records.

2.) To revoke any power of attorney at any time, each distribution facility shall:

a.) Contact Corporate Compliance to execute a **Notice of Revocation (Form FB03.02)**.

b.) The Notice of Revocation shall be signed by either:

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.02**
TITLE: Power of Attorney	**ISSUE DATE:**
	PAGE: 3 of 3

i.) The person who signed or was authorized to sign the power of attorney or by a successor; or

ii.) Whomever signed the most recent application for registration or re-registration.

c.) Written notice of revocation shall be given to the person whose power of attorney is being revoked.

d.) The notice of revocation shall be filed with the power of attorney being revoked.

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
614.757.5000 main

FA03.02

www.cardinalhealth.com

POWER OF ATTORNEY FOR DEA ORDER FORMS

_____ (Distribution Facility Name)
_____ (Address)
_____

DEA Number: _____

I, _____ the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S.C. 828) and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

_____
(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

_____
(Signature of Attorney-in-fact)

Witnesses:

1. _____

2. _____

Signed and dated on the ____day of _____, 20___,
_____.

Revised 3/03

FOIA Confidential Treatment Requested By Cardinal

CAH 022074

FB03.02

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
614.757.5000 main

CardinalHealth

www.cardinalhealth.com

NOTICE OF REVOCATION

_____ (Distribution Facility Name)
_____ (Address)
_____
_____

DEA Number: _____

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

_____
(Signature of person revoking power)

Witnesses:

1. _____

2. _____

Signed and dated on the ____day of _____, 20___,
at_____

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.03**
TITLE: Procedure for Filling Order Forms	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 4
RESPONSIBILITIES:	
APPROVALS: Approved by: _____ Date: 6-5-06 Stephen J. Reardon Vice President, Quality & Regulatory Affairs	

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.03**
TITLE: Procedure for Filling Order Forms	**ISSUE DATE:** **PAGE:** 2 of 4

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for filling order forms for the sale of Schedule I and II Controlled Substances.

SCOPE: Cardinal Health facilities registered with DEA for Schedule I and II Controlled Substances.

POLICY:

1.) The purchaser shall submit copy 1 (brown) and copy 2 (green) of the order form to the supplier and retains copy 3 (blue) on file.

2.) Order forms given by customers to contract drivers for delivery to the facility must be in a sealed envelope. The driver must have no knowledge of the contents of the order form. **Reference: DEA Correspondence July 18, 1996**

3.) The supplier shall fill the order, if possible and the supplier desires to do so.

4.) The supplier shall record on copies 1 (brown) and 2 (green):

a.) The number of commercial and bulk containers furnished on each item.

b.) The date on which the containers are shipped to the purchaser.

c.) If the order filler records incorrect information on the order form, the correction shall be made by drawing a line through and initialing and dating the incorrect entry and printing the correct information above it, or if space does not allow, at the bottom of the order form.

5.) An order that cannot be filled in its entirety may be filled in part and the balance supplied by additional shipments. Shipments must be within 60 days after its execution by the purchaser, except:

a.) Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

6.) The controlled substances must be shipped to the purchaser at the location printed by the administration on the order form, except:

a.) Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order form, as designated by the procurement officer when submitting the order.

7.) The facility or a "direct proprietary agent" must have the order form in hand before product is released. The direct proprietary agent can be a Cardinal Health:

a.) Sales representative

b.) Depot supervisor

c.) Driver (not common or contract)

Reference: DEA Correspondence April 20, 1998

8.) The supplier shall retain copy 1 (brown) of the order form.

9.) The supplier shall forward copy 2 (green) to the local DEA office in the area in which the facility is located via registered or certified mail, return receipt requested, or via Federal Express or UPS with a tracking number, at the close of the month during which the order was filled.

a.) If an order is filled by partial shipments, copy 2 (green) shall be forwarded either:

i.) At the close of the month during which the final shipment is made.

ii.) Or at the close of the month during which the 60-day validity period expires.

10.) The purchaser shall record on copy 3 (blue) of the order form:

a.) The number of commercial or bulk containers furnished on each item.

b.) The date the containers were received.

CardinalHealth

CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL

POLICY NO: DEA03.04

TITLE: Substitutions of Schedule II Controlled Substances

ISSUE DATE: 6-5-2006

PAGE: 1 of 2

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA03.04

TITLE: Substitutions of Schedule II Controlled Substances

ISSUE DATE:

PAGE: 2 of 2

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for making product substitutions on narcotic order forms.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The following substitutions of Schedule II controlled substances are acceptable:

a.) Generic product for generic product.

b.) Generic product for brand name product.

c.) Brand name product for generic product.

2.) The products to be substituted must be equivalent.

3.) The name and NDC number of the product shipped must be reflected on the order form.

4.) The purchaser must agree to the substitution and the facility must document the agreement.

Reference: DEA Correspondence July 29, 1992

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA03.05

TITLE: Faxing Narcotic Order Forms

ISSUE DATE: 6-5-2006

PAGE: 1 of 5

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.05**
TITLE: Faxing Narcotic Order Forms	**ISSUE DATE:** **PAGE:** 2 of 5

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for faxing narcotic order forms.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The facility must follow the DEA requirement for customer faxing of order forms, which are as follows:

   a.) The process of faxing an order form must involve a direct transmission from the customer to the Cardinal Health facility.

   b.) The order must not leave the facility until the original order form arrives at the facility.

2.) These procedures for the faxing of order forms from the customer shall be followed:

   a.) Customer faxes order form directly from the customer location to the distribution facility.

   b.) Operations Manager or designee checks order form for legibility and compliance and processes according to DEA regulations.

   c.) Operations Manager or designee contacts the customer if any discrepancies exist that would require the order form to be re-faxed.

   d.) Customer gives original order form to contract delivery driver in sealed envelope for delivery to distribution facility.

   e.) Operations manager or designee delivers faxed order form to the vault.

   f.) Vault clerk fills the order and files faxed order form.

   g.) Order is held until the original order form arrives at the distribution facility and is compared to the order.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.05**
TITLE: Faxing Narcotic Order Forms	**ISSUE DATE:** **PAGE:** 3 of 5

3.) The distribution facility must follow the DEA requirements for faxing order forms from a crossdock to the distribution center, which are as follows:

a.) The original order forms, when delivered to the crossdock, shall be in the possession of a Cardinal Health Pharmaceutical Distribution employee familiar with order form regulations.

b.) The order forms and a **DEA 222 Transmission Log (Form FA03.05)** shall be faxed to the division and order form receipt shall be verified to the log.

c.) Narcotic orders shall not be released at the crossdock unless there is a corresponding order form.

d.) The regulatory requirements for the processing of DEA Form 222 shall be strictly adhered to.

e.) The process must not be used unless:

i.) The crossdock is supervised by a Cardinal Health Pharmaceutical Distribution employee.

ii.) The Cardinal Health Pharmaceutical Distribution employee faxes the order forms.

iii.) The Cardinal Health Pharmaceutical Distribution employee maintains possession of the original forms until the order forms are exchanged for the controlled substances.

NOTE: Faxing of order forms from contract carrier crossdock locations must not be done by contract carrier employees.

4.) These procedures for the faxing of order forms from the crossdock shall be followed:

a.) Contract delivery drivers deliver original order forms in a sealed envelope to contract carrier crossdock supervisor.

b.) Crossdock supervisor delivers sealed envelopes containing order forms to Cardinal Health Pharmaceutical Distribution crossdock employee.

c.) Cardinal Health Pharmaceutical Distribution crossdock employee removes order forms from envelopes and completes **DEA 222 Transmission Log.**

d.) Cardinal Health Pharmaceutical Distribution employee faxes order forms to the distribution center.

i.) One transmission shall be used.

ii.) The **DEA 222 Transmission Log** shall be the last page of the fax.

e.) Fax is received in distribution center by Operations Manager or designee.

f.) Operations Manager or designee verifies faxed order forms received with information on the **DEA 222 Transmission Log.**

g.) Faxed copies of order forms are checked for legibility and compliance and are processed according to DEA regulations.

h.) If any discrepancies exist that would require order forms to be re-faxed, Operations Manager or designee contacts Cardinal Health Pharmaceutical Distribution crossdock employee.

i.) Cardinal Health Pharmaceutical Distribution crossdock employee places original order forms in a sealed envelope for delivery to the distribution center.

j.) Operations Manager or designee delivers faxed order forms to the vault.

k.) Vault clerk fills orders and files faxed order forms.

l.) Orders are held until original order forms arrive at the distribution center and are compared to the orders.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.05**
TITLE: Faxing Narcotic Order Forms	**ISSUE DATE:** **PAGE:** 5 of 5

NOTE: DEA may grant approval in emergency situations on a case-by-case basis for shipping the order before receiving the order form.

Reference: DEA Correspondence July 18, 1996, August 28, 1996.

FA03.05

CardinalHealth **DEA 222 TRANSMISSION LOG**

Date:_____

CUSTOMER NAME	NUMBER OF LINES	BLANK NUMBER	RECEIVED YES/NO

TOTAL NUMBER OF BLANKS TRANSMITTED:

TOTAL NUMBER OF BLANKS RECEIVED:

TRANSMITTED BY: _____

RECEIVED BY: _____

Revised 3/03

FOIA Confidential Treatment Requested By Cardinal

CAH 022087

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA03.06

ISSUE DATE: 6-5-2006

TITLE: Unaccepted and Defective Order Forms

PAGE: 1 of 5

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.06**
TITLE: Unaccepted and Defective Order Forms	**ISSUE DATE:** **PAGE:** 2 of 5

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for ensuring order forms accepted to be processed have correct information.

SCOPE: Cardinal Health facilities registered with the DEA for Schedule I and II Controlled Substances

POLICY:

1.) The facility shall comply with federal requirements applicable to the handling of narcotic order forms, which are as follows:

a.) No Order Form shall be filled if it:

i.) Is not complete, legible, or properly prepared, executed, or endorsed.

ii.) Shows any alteration, erasure, or change of any description.

b.) If an Order Form cannot be filled for any reason:

i.) The supplier shall return Copies 1 (brown) and 2 (green) to the purchaser with a statement as to the reason.

ii.) A supplier may for any reason refuse to accept the order. A statement that the order is not accepted shall be provided to the purchaser.

iii.) When received by the purchaser, Copies 1 (brown) and 2 (green) of the Order Form and the statement shall be attached to Copy 3 (blue) and retained in the files of the purchaser.

iv.) A defective Order Form may not be corrected: it must be replaced by a new Order Form in order for the order to be filled.

c.) Any information which is pre-printed on the order form shall not be altered in any way.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.06**
TITLE: Unaccepted and Defective Order Forms	**ISSUE DATE:** **PAGE:** 3 of 5

2. Order Forms shall be returned to the customer under the following circumstances:

   a.) The writing is illegible or it is otherwise impossible to identify a customer's registration number, items specified or quantities, or there is improper execution or endorsement.

   b.) There are alterations, erasures, or changes resulting in questions regarding the identity of the customer, customer's registration number, items or quantities.

   c.) Signature is omitted.

   d.) Sixty days have elapsed from the execution date by the purchaser.

   e.) The last line completed is greater than the last line specified.

   f.) The number of line items is greater than the total number of lines specified.

   g.) Customer voids a line.

   h.) "Last Line Completed" is omitted.

3.) Federal order forms which identify the customer's registration number, items and quantities, and which are properly signed but are incomplete or have minor errors may be corrected to the following extent:

   a.) The supplier's name, city state or zip code may be added when omitted by the customer.

   b.) The supplier's address, city, state or zip code may be corrected.

   c.) The date of the order may be added when omitted. Whenever possible, the postal date on the envelope shall be used.

   d.) It is permitted to add or change hydrochloride, sulfate, ampules, tablets, etc. if the customers order is correct in all respects except that it is specified in error.

e.) A letter or digit in the National Drug Code designation may be corrected if the controlled substance is described correctly, or the strength may be corrected if the quantity of controlled substance is not increased in any way.

f.) Order forms may be accepted when the customer has sent all three copies of the form to the supplier, but the customer's copy must be forwarded to the customer in advance of the product.

g.) Order forms received by the supplier without interleaf carbon may be accepted, but the supplier must insert a replacement carbon between the forms before making any entries on the form.

h.) If a form is received which lists a package amount which is unavailable, a lesser amount may be shipped (e.g. order is for package size 100, if unavailable may ship package size 50), or if a form is received which lists a package amount which is unavailable, different package sizes not to exceed the original amount may be shipped (e.g. ordered 1x1000, may ship 10x100).

i.) Lesser number of line items ordered than line items specified, if the supplier crosses out the remaining lines before filling the form.

j.) Last line completed has been incorrectly noted. The order form should not be rejected when it is clear that this is due to misinterpretation, rather than an attempt to facilitate diversion.

4.) A single item must be canceled for the following reasons, but the balance of the order may be shipped:

a.) If the number of packages, size of package, or strength has been altered by the person preparing the order form.

b.) If the item requested is discontinued or not listed, or is a non-controlled substance or is a controlled substance other than a Schedule I or II controlled substance.

c.) Strength is dittoed on the order form rather than designated.

d.) Strength is omitted (except trademark items when National Drug Code number is listed).

e.) Size of package incorrectly stated (quantity may be reduced).

f.) Size of package omitted.

Reference: DEA Correspondences 6/25/92, 4/25/93, and 9/14/95.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.07**
TITLE: Cancellation and Voiding of Order Forms	**ISSUE DATE:** 6-15-2006 **PAGE:** 1 of 2
RESPONSIBILITIES:	
APPROVALS: Approved by: _____ Date: 6-15-06 Stephen J. Reardon Vice President, Quality & Regulatory Affiars	

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.07**
TITLE: Cancellation and Voiding of Order Forms	**ISSUE DATE:**
	PAGE: 2 of 2

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for cancellation and voiding of order forms.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The following procedures shall be followed when a purchaser cancels all or part of an order form:

a.) The purchaser shall notify the supplier in writing of the cancellation.

b.) The supplier shall indicate the cancellation on copies 1 (brown) and 2 (green) of the order form by drawing a line through the canceled items and printing "Canceled" in the space provided for the number of items shipped.

2.) The following procedures shall be followed when the supplier voids all or part of an order form:

a.) The supplier shall notify the purchaser in writing on an **Order Form Rejection Notification (Form FA03.07)**.

b.) The supplier shall keep a copy of the order form and the notification.

c.) If the supplier cancels the entire form, the supplier shall return the form to the purchaser.

d.) The supplier shall indicate the cancellation on copies 1 (brown) and 2 (green) of the order form by drawing a line through the canceled items and printing "Canceled" in the space provided for the number of items shipped.

FA03.07

CardinalHealth

Date: _____
Customer Name: _____
Phone Number: _____

The Drug Enforcement Administration has established specific criteria for the acceptance of Federal Order Forms (DEA Form 222). In some cases, we are required to return the form to you and request a new or corrected form before shipping. In other cases, we can make minor changes and process the form for shipment.

Your Federal Order Form _____ was not complete and/or correct in all respects.
We have handled your form as follows:

☐ **The omissions and/or error indicated below is such that we are not permitted to process this form**

_____ Form is altered
_____ Our name and/or address is not acceptable as shown
_____ Sixty days has elapsed from date of execution
_____ Item listed is not a DEA Schedule II
_____ Item listed has been discontinued.
_____ Packages size is incorrect
_____ Product description is incomplete
_____ Number of packages or size is omitted
_____ Lines completed less than lines ordered
_____ Signature omitted
_____ Line number_____ canceled
_____ Last line completed left blank
_____ DEA number does not match what is on file
_____ DEA Form 222 was lost
_____ Permission to substitute was not granted for line_____
_____ Other

☐ **Form is being returned**

_____ Reference our phone conversation
_____ Please submit a new form
_____ Please revise attached form and return
_____ See example attached

☐ **Changes indicated below have been made (as permitted by DEA), and order has been shipped**

This action is for information purposes only. No action on your part is required.

_____ Our name and/or address has been completed as required
_____ Number of line items stated in box provided was more than actual listed. Blank line/s have been lined out
_____ All copies were sent, copy 3 is being returned
_____ NDC field was corrected for Line_____
_____ We modified the dosage form on line number _____. You requested _____, but it is only supplied as _____
_____ Line item number_____ was not correctable. We cancelled this line and processed rest of order Please submit new form for this item.

THANK YOU FOR YOUR COOPERATION

Rev 5/31/2006

From Completed By: _____

FOIA Confidential Treatment Requested By Cardinal

CAH 022095

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA03.08

TITLE: Procedure for Endorsing Order Forms

ISSUE DATE: 6-5-2006

PAGE: 1 of 2

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.08**
TITLE: Procedure for Endorsing Order Forms	**ISSUE DATE:** **PAGE:** 2 of 2

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for endorsing order forms.

SCOPE: Cardinal Health facilities, registered with the DEA for Schedule I and II Controlled Substances

POLICY:

1.) When an order form made out to any supplier who cannot fill all or part of the order within the time limitation is endorsed to another supplier, the following procedures shall be followed:

a.) The endorsement shall be made only by the supplier to whom the order was first made.

b.) The endorsement shall state (in the space provided on the reverse sides of copies 1 (brown) and 2 (green) of the order form) the name and address of the second supplier.

c.) The endorsement shall be signed by the person authorized to obtain and execute order forms on behalf of the first supplier.

d.) The first supplier shall not fill any part of an order on an endorsed form.

e.) The second supplier fills the order if possible and if the supplier desires to do so.

f.) The second supplier shall ship all substances directly to the purchaser.

2.) Distributions made on endorsed forms shall be reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier shall record the name, address and registration number of the first supplier.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA03.09

TITLE: Lost or Stolen Order Forms

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA03.09**
TITLE: Lost or Stolen Order Forms	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for lost or stolen order forms.

SCOPE: Cardinal Health facilities, registered with the DEA for Schedule I and II Controlled Substances

POLICY:

1.) If a purchaser ascertains that an unfilled order form has been lost, the purchaser shall:

a.) Execute another order form in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods ordered on the first order form were not received through loss of that order form.

b.) Retain Copy 3 (blue) of the second order form and a copy of the statement with Copy 3 (blue) of the first order form.

c.) Attach a copy of the statement to copies 1 (brown) and 2 (green) of the second order form sent to the supplier

d.) If the first order form is subsequently received by the supplier to whom it was directed these procedures shall be followed:

i.) The supplier shall mark it as "Not accepted".

ii.) The supplier shall return copies 1 (brown) and 2 (green) to the purchaser.

iii.) The purchaser shall attach it to copy 3 (blue) and the statement.

2.) Whenever any used or unused order forms are stolen or lost (besides in the course of transmission) by any purchaser or supplier, immediately upon discovery of the theft or loss, that person shall:

a.) Report it to the local office of the Drug Enforcement Administration stating the serial number of each form stolen or lost.

b.) If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, the supplier shall report the date or approximate date of receipt and the names and addresses of the purchasers.

c.) If an entire envelope of order forms is lost or stolen and the purchaser is unable to state the serial numbers of the order forms it contained, the purchaser shall report, in lieu of the numbers of the forms contained in the envelope, the date or approximate date the envelope was issued.

3.) If any unused order form reported lost or stolen is subsequently recovered or found, the local office of the Drug Enforcement Administration shall be notified immediately.

Cardinal Health **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA04.00**
TITLE: Required Reports to DEA	**ISSUE DATE:** 6-15-2006 **PAGE:** 1 of 6
RESPONSIBILITIES:	
APPROVALS: Approved by: _____ Date: 6-15-06 Stephen J. Rearden Vice President, Quality & Regulatory Affairs	

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA04.00**
TITLE: Required Reports to DEA	**ISSUE DATE:** **PAGE:** 2 of 6

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements to report transactions, thefts, drug destructions and suspicious orders to the DEA and DEA ARCOS Unit.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) ARCOS Reports

a.) Each facility who handles controlled substances in Schedule I and II and narcotics in Schedule III must report to the ARCOS Unit as follows:

i.) Annual inventory, taken at close of business December 31.

ii.) Initial inventory, taken on the effective date that a substance becomes reportable.

iii.) Transaction reporting, quarterly or monthly with DEA permission.

b.) Reports shall be submitted within 15 days after the end of the report period.

i.) Send reports by certified or registered mail, return receipt requested to:

Drug Enforcement Administration
ARCOS Unit
P.O. Box 27273
Washington, D.C. 20038-7273

ii.) Send reports via commercial carrier such as Federal Express or United Parcel Service to:

DEA Headquarters
Attn: ARCOS Unit
2401 Jefferson-Davis Highway
Alexandria, VA 22301

c.) For authorization to report ARCOS data from other than a registered location, a central reporting identifier must be obtained from the ARCOS Unit.

Reference: Exhibit EA04.00 Guide To Handling ARCOS Transactions

2.) Order Forms

a.) The facility shall send Copy 2 of the narcotic order form to the local DEA office via registered or certified mail, return receipt requested, or via Federal Express or UPS with a tracking number, at the close of the month during which the order was filled.

b.) For an order filled by partial shipments, Copy 2 shall be forwarded at the close of the month during which the final shipment is made or after the 60-day validity period expires.

3.) Drug Thefts and Losses

a.) The facility must notify by telephone the local DEA field office of any theft or significant loss upon discovery of the theft or loss.

b.) A **Report of Theft or Loss of Controlled Substances, DEA Form 106 (Form FA04.00)** must be completed.

c.) The **DEA Form 106** must be submitted to the local DEA office via registered or certified mail, return receipt requested, within seven (7) days of the incident.

i.) Reporting in-transit losses is the supplier's responsibility.

ii.) The customer must report for shipments for which the facility has a signed receipt.

NOTE: The reporting of inventory variances on DEA Form 106 must be carefully evaluated. Variances which are the result of record keeping or order filling errors need not be reported. Actual discrepancies which are the result of a theft or significant loss must be reported.

Reference: DEA Correspondence May 13, 1999

d.) The completed **DEA Form 106** shall be distributed as follows:

i.) The original and duplicate copies shall be submitted to the local DEA office via registered or certified mail, return receipt requested, within seven (7) days of the incident.

ii.) The facility shall send a copy of the **DEA Form 106** to their state agency via registered or certified mail, return receipt requested, if required. See **Exhibit EB04.00** for State reporting requirements

iii.) A copy and all documents regarding the incident shall be retained on file, at the Cardinal Health facility, in accordance with applicable Federal and State regulations.

iv.) A copy shall be forwarded to the ARCOS recorder at the facility for ARCOS reporting.

v.) A copy shall be included in the month-end packet sent to the Regional Compliance Manager.

e.) ARCOS reportable items filed on **DEA Form 106** must also be reported to ARCOS.

4.) Drug Destructions

a.) If there are controlled substances to be destroyed the facility shall notify the DEA special agent in charge on **Registrant Inventory of Drugs Surrendered, DEA Form 41 (Form FB 04.01)**.

i.) The form shall be completed in triplicate.

ii.) The facility shall follow the instructions from the special agent in charge for how the drug destruction will be handled.

NOTE: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.

b.) Destruction of ARCOS reportable items filed on **DEA Form 41** must also be submitted to ARCOS.

c.) Unsaleable merchandise may be sent to third party firms for destruction.

i.) The facility must create a Debit Memo to the third-party firm.

ii.) Third-party firm destroys the product and files the **DEA Form 41**.

d.) **DEA Form 41** shall be used for documenting a non-recoverable liquid controlled substance loss when the container accidentally breaks.

i.) Pieces of the broken bottle do not need to be retained as evidence of the accident.

ii) Any loss of an ARCOS reportable item must also be reported to ARCOS using code Y and the local DEA field office's DEA number.

iii) **Do Not Submit the 41 to DEA.**

5.) Suspicious orders

a.) Wholesalers must design and operate a system that will disclose suspicious orders to the wholesaler.

i.) The facility must inform the DEA field office in the area of all suspicious orders.

ii.) Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency.

b.) Wholesalers must establish written criteria of what constitutes a suspicious order.

i.) The criteria must be reasonable and based upon customer purchasing patterns.

ii.) Each facility must adhere to the established criteria in monitoring orders.

iii.) Monitoring system may be either computerized or manual.

c.) Each facility shall submit to the local DEA office on a monthly basis, via registered or certified mail, return receipt requested, or via Federal Express or UPS with a tracking number, an Ingredient Limit Report **(Exhibit EC04.00)**.

NOTE: The report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

d.) On a daily basis, each facility shall monitor and identify individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history.

i.) The facility shall notify the local DEA field office, if possible before the order is shipped.

ii.) A copy of all such orders must be maintained in the facility's suspicious order file.

iii.) A Regulatory Agency Contact Form **(Form FC04.00)** must be completed, noting any specific instructions from the DEA.

e.) Dosage Limit Charts **(Exhibit ED04.00)** must be posted in the cage and vault.

f.) Each location for the products listed on the charts shall be marked with the hospital and retail dosage limits.

EA04.00

CardinalHealth

Guide to Handling ARCOS Transactions

Guide To Handling ARCOS Transactions

Table of Contents

GUIDE TO HANDLING ARCOS TRANSACTIONS

Introduction

The Automation of Reports and Consolidated Orders System (ARCOS) was developed by the DEA to report inventories of selected controlled substances and increases and decreases to these inventories. The selected controlled substances are Class II and III narcotics.

Transactions can be reported electronically via tape or diskette, or manually using ARCOS Form 333. In most divisions, a majority of the ARCOS records are created automatically during the receiving, invoicing and crediting processes. Other records must be created by manually entering the data into the ARCOS Maintenance Menu.

A report of all ARCOS transactions generated by the system is available for review. Depending on the system, this may be daily or monthly. Prior to submission to ARCOS, erroneous transactions can be changed or corrected using the ARCOS Maintenance Menu.

Distributors are required to take an annual inventory of each reportable controlled substance on December 31st and file it with ARCOS no later then January 15th of the following year. Increases and decreases in the inventory of each reportable controlled substance must be reported on a monthly basis and filed with ARCOS no later than the 15th of the month following the end of the reporting period.

For automated reporters, a tape of these transactions is sent to ARCOS, with a hardcopy report maintained at the division for two years. This report is useful when researching errors identified by ARCOS as it contains additional information, including item number and description, invoice number and customer or vendor number. For manual reporters, hand-written transactions are submitted to ARCOS on Form 333. One copy of the form is maintained at the division for two years.

ARCOS 'reads' the tape and generates a report entitled "ARCOS Daily Transactions Processing Error Report." The report will either acknowledge that no errors were found, or will list the transaction records in error, with the error code, description of the error and a correction number. Corrections must be made and the transactions resubmitted. Error reports must be maintained at the division for two years.

All media submitted to ARCOS must have a barcode label attached. Submissions must be made as described below:

ARCOS reports sents via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) must be sent to:

DEA Headquarters
Attn: ARCOS Unit
2401 Jefferson-Davis Highway
Alexandria, VA 22301

ARCOS reports sent via the U.S. Postal Service must use the following address:

Drug Enforcement Administration
ARCOS Unit
P.O. Box 27273
Washington, D.C. 20038-7273

Inquiries can be made to the ARCOS Unit at (202) 307-8600.

What to do before sending a report to ARCOS

The Distrack system has a daily report of ARCOS transactions with the ability to make changes, additions and deletions prior to the submission of the transactions to ARCOS. Instructions can be found in the ARCOS Maintenance Section.

In the review process, look for

- DEA numbers that do not fit the typical format (2 letters followed by 7 numbers),
- blank numbers that do not fit the typical format (9 digit number),
- items that are not ARCOS reportable,
- quantities that appear to be excessive or out of the ordinary, and
- inventory adjustments.

Keep in mind that the only transactions that need to be reported to DEA are those that document an actual transfer of product. Records created by inventory adjustments when the product is moved from the live inventory to the morgue inventory do not represent a transfer of product and must be deleted. Credit and rebills for contract/chargeback purposes and dropship billings are two more examples of financial transactions that do not represent the actual transfer of product.

If changes need to be made to an Associate's DEA registration number, the modification should also be made in the Customer or Vendor Master File so that future transactions do not contain the same error.

ARCOS reportable items that are documented as lost-in-transit or stolen on DEA Form 106 or as destroyed on DEA Form 41, need to be reported as transactions to ARCOS. Since forms to the DEA are submitted manually, ARCOS records are not generated by the system and need to be created.

For an item lost-in-transit,

- use the date of the sale,
- the NDC and quantity of the item,
- the associate DEA number as the original sale record,
- a transaction code of X.

For a theft,

- report the date the theft occurred or was identified,
- the NDC and quantity of the item,
- a transaction code of T.
- The associate DEA number must be left blank.

For a destruction of a controlled substance (destroyed at your registered location),

- use the date the destruction occurred,
- the NDC and quantity of the item,
- a transaction code of Y
- the associate DEA number for the regional DEA office.

Product sent to a third-party for destruction is documented as a sale to the company. ARCOS records must be created through the invoicing process using transaction code S. If these activities occurred during a previous month, they should be reported as late transactions using the I code in the Action Indicator column.

ARCOS reportable items that are returned from an unknown source must be documented as an addition to the inventory. This record is not generated by the system and must be created.

For an unsolicited return,

- use the date the product was received at the facility,
- the NDC and quantity of the item,
- a transaction code of V,
- the associate DEA number of UNKNOWN

The following are some sample lines from a report from the Distrack system., with a summary of what it means.

GR8050

THE MUNSTER COMPANY

ARCOS TRANSACTION EDIT REPORT

DAILY TRANSACTIONS CALLED FOR BY SYC693 - END OF DAY PROCESSING

PERIOD ENDING 3/19/98

TRANSACTION YYMM	TRANSACTION IDENT.	TRANSACTION CDE	TRANSACTION DATE	ITEM NUMBER	NDC NUMBER	DESCRIPTION	ASSOC. ID NO.	ASSOC. DEA REG. NO.	BLANK FORM NO.	CORRECTION NUMBER	D C	QTY	BILL-ACCT #	SHIP-ACCT#	INVOICE NUMBER	INVOICE DATE	MFG#	PO#	ADJ	C/M#	SRC
9803	6499	P	3/19/98	181084	00034-0517-25	MS CONTIN CR 100MG 25/JD PFC C2	5570	PT0226820	973652612			12	000000	000000	0000000	0/00/00	03570	49623		0000000	52
9803	6503	S	3/19/98	104134	00074-3142-01	NEMBUTAL SOD 18.2MG 480ML C2		UNKNOWN				1	000000	000000	0000000	0/00/00	05000	00000	50	0000000	54
9803	6650	S	3/19/98	148976	59630-0100-04	PROTUSS 120ML GRAPE HOR C3	381914	AB3010763				2	381914	381914	4207012	98/03/19	00000	00000		0000000	51

Field Name	Description	Definition	Function
YYMM	year and month	4 digit code to identify the year and month of the reporting period	reported to ARCOS to identify the reporting period
IDENT	transaction identifier	sequential number assigned by the reporting registrant to each transaction record	reported to ARCOS to identify the transaction
CDE	transaction code	single-character field which identifies each specific ARCOS-reportable activity. The entire list of available codes is on the next page.	reported to ARCOS to identify the activity
DATE	transaction date	the actual date on which the activity occurred	reported to ARCOS to identify the date of the activity
ITEM NUMBER	item number	number assigned by the company to a particular SKU	used by the division for research and identification purposes
NDC NUMBER	National Drug Code number	11-character code that identifies controlled substance products	reported to ARCOS to identify the item
DESCRIPTION	item description	description of the item including size, strength, and finished form	used by the division for research and identification purposes
ASSOC. ID NO.	associate identification number	number assigned by the company to the vendor or customer participating in the transaction	used by the division for research and identification purposes
ASSOC. DEA REG. NO.	associate DEA registration number	9-character field identifying the customer or supplier with which the transaction took place	reported to ARCOS to identify the other party in the transaction
BLANK FORM NO.	narcotic order form (DEA 222) number	9-character field for the number of the order form	reported to ARCOS for CII items
CORRECTION NUMBER	correction number	unique sequential number assigned by ARCOS to an erroneous transaction	reported to ARCOS for reprocessing a corrected transaction
DC	action indicator (formerly the delete indicator)	a single character field which initiates three different ARCOS data base operations	reported to ARCOS when deleting or revising previously submitted and accepted transactions, or when inserting unreported transactions from previous months.

Field Name	Description	Definition	Function
QTY	quantity	numeric field containing the number of packages, weight, or volume being reported	reported to ARCOS to identify the quantity
BILL – ACCT #	Bill-to account number	customer number assigned by the company to the account that was invoiced for the product(s) in this transaction	used by the division for research and identification purposes
SHIP – ACCT #	Ship-to account number	customer number assigned by the company to the account that was delivered the product(s) in this transaction	used by the division for research and identification purposes
INVOICE NUMBER	invoice number	the number assigned to the invoice that reflects the sale to the customer	used by the division for research and identification purposes
INVOICE DATE	invoice date	the date the invoice was created. Usually matches the transaction date.	used by the division for research and identification purposes
MFG #	vendor number	number assigned to the vendor from whom the product was purchased	used by the division for research and identification purposes
PO#	purchase order number	number assigned to the order under which the product was purchased	used by the division for research and identification purposes
ADJ	inventory adjustment code	the code assigned to the adjustment to indicate the disposition of the inventory	used by the division for research and identification purposes
C/M#	credit memo number	the number assigned to the credit memo that reflects the return of the product from the customer	used by the division for research and identification purposes
SRC	source	identifies where the information came from that created the transaction record	used by the division for research and identification purposes

TRANSACTION CODES

(FROM PAGE 5-6 OF THE ARCOS REGISTRANT HANDBOOK)

INVENTORY TRANSACTION CODES

1	SCHEDULE CHANGE INVENTORY
3	YEAR-END INVENTORY
4	YEAR-END IN-PROCESS INVENTORY (MANUFACTURERS ONLY)
5	SPECIAL INVENTORY
8	NO YEAR-END INVENTORY

ACQUISITION TRANSACTION CODES (INCREASES TO INVENTORY)

P	PURCHASE OR RECEIPT
R	RETURN
V	UNSOLICITED RETURN
W	RECOVERED WASTE (MANUFACTURERS ONLY)
M	MANUFACTURED (MANUFACTURERS ONLY)
G	GOVERNMENT SUPPLIED
L	REVERSING (MANUFACTURERS ONLY)
J	RETURN OF SAMPLE TO INVENTORY (MANUFACTURERS ONLY)

DISPOSITION TRANSACTION CODES (DECREASES TO INVENTORY)

S	SALE, DISPOSITION, OR TRANSFER
Y	DESTROYED
T	THEFT
N	NONRECOVERABLE WASTE (MANUFACTURERS ONLY)
U	USED IN PRODUCTION (MANUFACTURERS ONLY)
Z	RECEIPT BY GOVERNMENT (SEIZURES, SAMPLES, ETC.)
Q	SAMPLING (MANUFACTURERS ONLY)
K	USED ON PREPARATIONS (MANUFACTURERS ONLY)

MISCELLANEOUS TRANSACTION CODES

F	REORDER DEA-333 FORMS
X	LOST IN TRANSIT
7	NO ARCOS ACTIVITY FOR THE CURRENT REPORTING PERIOD

What To Do When A Report Is Received From ARCOS:

1. Identify the time period of the errors.
2. Retrieve the monthly report for that time period, to be used as reference.
3. Review the error code and the necessary correction action.
4. Determine if the error needs to be resubmitted. (Is it an ARCOS reportable item? Does the record reflect an actual transfer of product?)
5. Research any information pertinent to the type of error (invoice, receiver, credit memo, narcotic blank, etc.)
6. Create correction transactions in the ARCOS Maintenance Menu of the computer system. These transactions should be made in the current month's tape and not in the month of the original submission.
7. Make any necessary changes to the customer/vendor file or item file that could prevent future errors.

EDIT ERRORS REPORT

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
A R C O S – 2
DAILY TRANSACTIONS PROCESSING

ERROR REPORT

CARDINAL HEALTH
14601 COUNTY ROAD #212
FINDLAY, OH 45840

ERRORS FOR CONTROL RECORD = = > RM1313666*043098M

RM1313666S 5045800340500000192RD010495998047570704289800000102000009804011749
E77 NDC NUMBER ISN'T ARCOS REPORTABLE. DON'T SUBMIT CORRECTED TRANSACTION.
CORRECTION NUMBER: 00000102

RM1313666P 0000802580100000020 PA3037982962156755040798000001030000 9804012347
E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER
CORRECTION NUMBER: 00000103

Errors for Control Record

RM1313666	SUBMITTING REGISTRANT NUMBER
*	ASTERISK
043098	LAST DATE OF THE REPORTING PERIOD REPORT MEDIA (T=TAPE)
M	REPORTING FREQUENCY (M=MONTHLY)

LINE 1

RM1313666	REPORTING REGISTRANT NUMBER (DIVISION)
S	TRANSACTION CODE
50458003405	NATIONAL DRUG CODE (11 DIGITS)
00000192	QUANTITY (8 DIGITS)
RD0104959	ASSOCIATE REGISTRATION NUMBER (CUSTOMER OR VENDOR)
980475707	DEA ORDER FORM NUMBER (BLANK NUMBER, 9 DIGITS)
042898	TRANSACTION DATE
00000102	CORRECTION NUMBER
00009804	YEAR/MONTH OF REPORT
011749	TRANSACTION IDENTIFIER

LINE 2

E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER

LINE 3

CORRECTION NUMBER: 00000102

ERROR CODES
(FROM PAGE 7-5 OF THE ARCOS REGISTRANT HANDBOOK)

E01 REPORTING REGISTRANT NUMBER DOESN'T MATCH THE ONE ON THE CONTROL RECORD
E06 DELETE INDICATOR FIELD MUST BE BLANK OR MUST BE THE LETTERS "A", "D", OR "I"
E07 DELETE INDICATOR FIELD MUST BE BLANK IF A CORRECTION NUMBER IS PRESENT
E12 TRANSACTION DATE CONTAINS AN INVALID MONTH AND/OR AN INVALID DAY
E13 TRANSACTION DATE MUST BE THE LAST DAY OF THE REPORT MONTH OR QUARTER
E14 TRANSACTION CODE REQUIRED A YEAR-END DATE IN THE TRANSACTION DATE FIELD
E15 TRANSACTION DATE IS LATER THAN THE RUN DATE OF THE ARCOS 2 EDIT PROGRAM
E16 TRANSACTION DATE IS NOT WITHIN THE REPORTING REGISTRANTS REPORT PERIOD
E17 TRANSACTION DATE ISN'T WITHIN THE 2 YEAR DATE RANGE OF THE ARCOS SYSTEM
E21 CORRECTION NUMBER ENTERED IN INVALID. IT MUST BE NUMERIC
E22 CORRECTION NUMBER IS NOT IN THE ERROR FILE
E25 THE ARCOS EDIT STILL FOUND ERRORS ON THE CORRECTION TRANSACTION
E28 DATA ENTERED IN THE QUANTITY FIELD IS INVALID. IT MUST BE NUMERIC.
E31 THE UNIT VALUE ENTERED CANNOT BE USED WITH THE ENTERED NDC NUMBER
E32 UNIT VALUE MUST BE BLANK, "D", "K", "1", "2", "3", "4", "5", "6"
E35 STRENGTH MUST BE BLANK FOR BULK FINISHED OR 0001 TO 1000 FOR BULK RAW
E36 STRENGTH IN INVALID. STRENGTH MUST BE BLANK OR NUMERIC
E40 TRANSACTION CODE IS INVALID. SEE THE ARCOS MANUAL FOR VALID CODES.
E41 TRANSACTION CODE IS RESERVED FOR DRUG MANUFACTURERS ONLY
E42 TRANSACTION CODE REQUIRES ASSOCIATE REGISTRANT NUMBER TO BE BLANK
E43 ASSOCIATE REGISTRANT NUMBER REQUIRES TRANSACTION CODE "Y", OR "G", OR "Z"
E44 TRANSACTION CODE CONFLICTS WITH THE NDC NUMBER'S CSA SCHEDULE
E45 TRANSACTION CODE REQUIRES AN ASSOCIATE REGISTRANT NUMBER ENTRY
E46 ASSOCIATE REGISTRANT NUMBER IS INVALID FOR TRANSACTION CODE "Y/G/Z"
E47 ASSOCIATE REGISTRANT NUMBER CAN'T EQUAL REPORTING REGISTRANT NUMBER
E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER
E49 ASSOCIATE REGISTRANT NUMBER IS INVALID FOR THE TRANSACTION CODE
E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED
E53 THE ORDER FORM NUMBER IS REQUIRED FOR SCHEDULE 1 & 2 DRUGS
E60 TRANSACTION CODE 1 – AN INVENTORY RECORD ALREADY EXISTS
E61 TRANSACTION CODE 3 OR 8 – YEAR-END INVENTORY AMOUNT ALREADY EXISTS
E75 THE NDC NUMBER IS INVALID, IT CONTAINS ONE OR MORE SPACES
E76 THE NDC NUMBER IS NOT IN THE DRUG FILE
E77 NDC NUMBER ISN'T ARCOS REPORTABLE. DON'T SUBMIT CORRECTED TRANSACTION

ARCOS Transaction Maintenance/AS400

Through the modified ARCOS Transaction Maintenance Menu, changes can be made not only to transactions from the current month, but also transactions to previous months. All of the maintenance must be done in the current reporting period to ensure that changes are added to the current month's tape.

Since transactions can now be from a variety of months (previous or current), the transaction ID will consist of the year/month (YYMM) and sequence number (Seq), as shown on the far left of each transaction.

Screen 1

From the ARCOS File Maintenance Menu, you must select the file type and enter the report reference date, as well as an access path. The file type can either be Monthly (M), Annual (A), or Special (S). A majority of the time, this selection will be M. The report reference date is the last date of the reporting period you have selected. For example, if you want to look at the records for May 1999, then you would enter M and 05311999. Through your selection of an access path, you make the determination of how the transactions are sorted. Entering a 'starting at' value can help to limit your search, but is not required. By leaving that field blank, the search will begin with the lowest value of your selected access path. The options for access path are:

1 = Corporate Item Number
2 = Blank Number
3 = NDC Number
4 = Customer Number
5 = Vendor Number
6 = DEA Number
7 = Sequence Number

Screen 2

After selecting the file type, the reference date, the access path and pressing enter, the next screen is displayed. The columns appearing on the screen are:

Sel = select transaction to update
Seq # = transaction ID
Trans Date = transaction date
Cd = transaction code
Dc = action indicator (only used for late, adjusted, and deleted transactions)
Cst/Vnd = customer or vendor number, depending on which access path was chosen
NDC/Item # = NDC or item number, depending on which access path was chosen
Quantity = transaction quantity
ASS Reg # = Associate registration number (DEA number of the other party involved in this transaction)
Blank # = order form number (required for CII transactions only)

If you choose a 'starting at' value in Screen 1, that equals a valid value for that access path, then that value will be highlighted in all of the transactions where it is included.

You can scroll through transactions with a higher value for the access path, but in order to view transactions with a lower value, you must enter another value into the 'start at' field at the top of the screen and press F8. This 'start at' value is associated with the access path code selected on Screen 1. To select an alternative access path, press F12 to return to Screen 1.

To make a change to a transaction, enter '2' in the 'Sel' column and press enter. This will display the Change/Delete Current window. Changes can be made to any fields that are underlined. After completing the changes, press 'enter' and the transaction will be verified for accuracy and will be updated in the file. This function can be used for any transaction in the current batch including the current month's transactions, as well as any added, late or corrected transactions that have been entered.

To delete a transaction, enter '4' in the 'Sel' column and press 'enter'. This will display the Change/Delete Current window. No information can be entered into this pop-up window. Press F4 to accept the delete. This function can be performed for any transaction that is displayed in the current batch that is not already deleted, this includes the current month's transactions, as well as any added, late or corrected transactions that have been entered. Deleted transactions will be displayed with an 'X' in the Dc column.

To add (current month) transactions, press (F6). This will display the Add Transaction pop-up window will appear requesting the required information. After completing the window, press <enter> and the transaction will be checked for accuracy and a transaction ID will be assigned. This add function can only be used for transactions that have occurred in the current month. Adding transactions from previous months is done using F14.

To add late (previous months) transactions, press (F14). This will display the Late Transaction pop-up window will appear requesting the required information. *You must assign a transaction ID that includes the YYMM of the transaction and an original sequence number.* The YYMM *must* be from a previous month. After completing the window, press <enter> and the transaction will be checked for accuracy and will be added to the batch. Late transactions will be noted with an 'I' in the Dc column. This function can only be used for transactions that have occurred in previous months.

To add corrected (DEA specified) transactions, press (F15). This will display the Correction Transaction pop-up window will appear requesting the required information. These transactions are identified on the ARCOS-2 Error Report. *The correction transaction record must contain 1) all the fields that were correct on the original submission including the original transaction identifier, 2) the corrected field(s), and 3) the correction number.* The YYMM *must* be from a previous month. After completing the window, press <enter> and the transaction will be checked for accuracy and will be added to the batch. Corrected transactions will be noted with a correction number under the Corr# column. This function can only be used for transactions that have been identified as errors by the DEA and must not have occurred in the current month.

To adjust (previous months) transactions, press (F20) This will display the Adjustment, Deletion pop-up window will appear requesting the required information. This is to correct mistakes on previously submitted transactions. Once these are identified, wait until the error report is received from ARCOS. If the transaction appears on the error report, a correction must be made using F15. If the transaction does not appear on the error report and was accepted by ARCOS, an adjustment must be made using F20. The first record created will be coded 'D' in the Dc column. You will then be prompted to adjust the transaction to reflect correct information. The second record will be coded 'A' in the Dc column.

To delete (previous months) transactions, press (F21) This will display the Delete, Previous pop-up window will appear requesting the required information. This is to delete transactions that were previously submitted but should not have been. The record will be coded D in the Dc column.

To unfold the screen, press (F10). This will expand a single transaction to two lines and include the customer name and the item description.

To select all transactions that meet a specified value in an access path, press (F7). This will put a '2' in the 'Sel' column. If the transactions span for more than one page, you must page forward to the last page of the highlighted transactions to select all of these transactions. If you press F7 without first paging forward, you will only select the specified transactions from the first page.

To mass update, press (F5). This will display the Mass Change pop-up window. From this window you have the option to change the NDC, DEA number or Blank number from the first transaction you selected to another value. It is recommended that mass changes only be made to the field that was selected in the access path.